choice

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ASSESSMENT PATHWAYS FOR COMPLEMENTARY MEDICINES CONSULTATION

Submission to the Therapeutic Goods Administration

ABOUT US

Set up by consumers for consumers, CHOICE is the consumer advocate that provides Australians with information and advice, free from commercial bias. By mobilising Australia's largest and loudest consumer movement, CHOICE fights to hold industry and government accountable and achieve real change on the issues that matter most.

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INTRODUCTION

Aggressive marketing, celebrity endorsements and ingrained cultural and traditional values draw consumers to complementary medicines. But do the statements made about complementary medicines live up to their claims?

Just because a product is considered low risk, this does not mean it should be sold to consumers with misleading claims as to its efficacy. CHOICE believes that the current labelling system and regulatory framework does not provide clear, quality information to consumers on the efficacy of therapeutic products. Research shows that consumers do not understand the current labelling system, and the market is crowded, with over 11,000 'listed' products.

The introduction of a new pathway for complementary medicines approval will help consumers better understand the efficacy and claims of products on face value. This new assessment pathway will signal to consumers that a product is effective and has been scientifically proven to do what it says it does. If properly implemented, consumers should find it easier to avoid products which have not been independently assessed, should they choose to do so.

However, it is vital that any new measures are thoroughly consumer tested. Any new system ultimately needs to improve consumers' ability to quickly and accurately judge the efficacy of complementary medicines.

1. Most consumers do not understand 'listed' and 'registered'

Most consumers do not understand or are unaware of the current Therapeutic Goods Administration (TGA) labelling, assessing and testing system. CHOICE research found 80% of consumers had never even noticed the 'listed' and 'registered' labelling (AUST-L and AUST-R) on complementary medicines.

CHOICE conducted a nationally representative survey of 1052 Australians in December 2016, asking them about their knowledge of listed and registered medicines:[1]

- 80% of respondents never noticed the 'AUST-R' and 'AUST-L' numbers
- 7% weren't sure if they had seen the 'R' and 'L' numbers
- 13% were aware of the 'R' and 'L' labels

CHOICE also asked those consumers who were aware of TGA labelling if they understood the meaning of 'listed' and 'registered'. Of the 142 people (13%) who were aware of the labels, 43% believed that 'listed' products had been evaluated by the TGA for efficacy and 23% weren't sure.

CHOICE also asked consumers about their concerns about herbal medicines and dietary supplements. The high level of concern shows a need for better and clearer labelling so that consumers can adequately address their concerns regarding testing at the point of purchase.

- 77% were concerned that many herbal medicines and dietary supplements hadn't been tested by the TGA
- Only 7% were unconcerned that many supplements weren't tested

[1] CHOICE Consumer Pulse December 2016 is based on a nationally representative survey of 1,052 Australian households. Fieldwork was conducted from the 2nd to the 12th of December, 2016. The survey was designed and analysed by CHOICE with fieldwork and sample provided by The ORU. The ORU are ISO 20252 and 26362 accredited and are full AMSRO members.

2. Consumers need clear and simple labelling

Claiming evidence under the proposed new pathway

CHOICE supports differentiation for complementary medicines that have been scientifically proven and have undergone independent assessment to verify their claims. Labelling this assessment pathway in the form of a tick or other logo would help consumers easily identify which products are proven to work.

A prominent visual identifier confirming a product's efficacy would provide a small counterpoint to aggressive and pervasive marketing, including high profile celebrity endorsements, and the sometimes unhelpful and inaccurate instore advice given to consumers. CHOICE found that 82% of consumers want labelling to clearly reflect the level of assessment undertaken by the TGA.[2] The current system does not allow consumers to have this level of detail when purchasing a product.

It is also vital that there is transparency in the assessment process to strengthen consumer confidence and trust in the new pathway. An assessment of evidence by the TGA should be provided in a central public place, such as on the TGA website. A system similar to the current requirements for prescription medicines would be appropriate, where evaluations are placed on the Australian Public Assessment Reports for prescription medicines (AusPARs) web page.

Case study: CHOICE mystery shop of advice from pharmacists

CHOICE recently found that a significant number of pharmacists were recommending products for stress that were not evidence based.[3] The mystery shop, conducted in January 2017, demonstrates consumers' willingness to trust products purchased in a pharmacy, from a pharmacist, despite many of those products lacking evidence for their efficacy.

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[2] CHOICE Consumer Pulse December 2016

[3] This work was conducted by CHOICE Consumer Insights. An accredited fieldwork provider, Lonergan Research and Mystery Shopper, was commissioned to recruit shoppers and complete the mystery shopping. Lonergan Research and Mystery Shopper are accredited with the Mystery Shopping Providers Association (MSPA) and abide by MSPA Code of Ethics. Shoppers were recruited to complete shops Australia wide, ranged in ages from 18 to over 65, male and females. Each shopper was incentivised to participate. The results of each mystery shop were captured by an online survey and verified before being quality checked and verified by CHOICE. All analysis and reporting has been conducted by CHOICE Consumer Insights, who abide by the AMSRS code of professional conduct and ethics. Fieldwork was conducted between January 1st to the 25th, 2017.

CHOICE sent mystery shoppers into 240 pharmacies across Australia, including major pharmacies Priceline, Chemist Warehouse and Terry White Chemmart. Each shopper approached the prescription dispensing counter and asked the pharmacist for advice, stating "I've been feeling really stressed lately, is there something that you can recommend?"

Only 3% of shoppers were advised to see their doctor and 1% were directed to the vitamin section without being accompanied by the pharmacist. The majority of shoppers were given a recommendation a product. Of those shoppers who were recommended a product:

- 46% were recommended B vitamin products, which has some proven effects
- 26% were recommended Bach flower remedies, which has no proven effects
- 15% were recommended valerian, evidence is mixed as to whether this would address stress
- 13% were recommended an antihistamine, evidence is mixed as to whether this would address stress
- 12% were recommended St John's Wort, which isn't proven to reduce stress but can assist with mild to moderate depression
- 8% were recommended magnesium supplements, little evidence exists that this would address stress
- 3% were recommended homeopathic remedies, there is strong evidence that homeopathic remedies will not assist with anything
- Other products recommended included passionflower, withania (Indian ginseng), lemon balm, hops, green tea and ginkgo biloba.

Beyond AUST-L and AUST- R labels which have low consumer recognition, there was no way for shoppers to tell if a product's has undergone independent assessment for efficacy at the point of sale other than through claims made by the pharmacist. Particularly concerning were claims made about the Bach flower remedy by pharmacists:

- 57% were assured of its efficacy
- 30% were assured it is effective for most users
- 18% said it was **scientifically proven to work**

The introduction of a new assessment pathway and associated 'stamp of approval' could assist consumers in assessing a product's efficacy on face value, as a supplement to advice provided by their pharmacist. A logo and new pathway may also assist pharmacists in assessing and recommending the thousands of complementary medicines available in-store.

However, for any new labelling to work, it must be tested to ensure that the message is clear to consumers, placed in a prominent and consistent place on all labels to allow product comparison and promoted widely through advertising to make consumers aware of its meaning.

Implementing a list of permitted indications

CHOICE supports a move to standardise indications of efficacy made on products. Claims such as “prevents”, “treats” and “alleviates” on products that have not undergone independent assessment at best serve to sell consumers products they don’t need and at worst pose serious health risks, as someone either buys something that can interact with other medications or is delayed from seeking genuinely effective treatment

Implementing permitted indications may also help reduce the number of misleading and deceptive claims on complementary medicine products. Of 473 cases investigated in 2015-16, 80% of medicines had verified breaches.[4] Worryingly, the most common problem was a failure to provide scientific evidence that a product did what it claimed.

The placement and display of permitted indications must be standardised and easy for consumers to read, including ensuring the logo is visible to consumers when displayed on pharmacy shelves. Any new indications should be tested with consumers to ensure that they meet the needs of consumers and health professionals. The framework suggested in the consultation paper should undergo testing to ensure suitability.

Consumer testing

The TGA should thoroughly test logo designs with consumers, pharmacists, and other health professionals to ensure that they are clear and easy to understand. A logo, such as a tick, would help products with scientifically proven benefits stand out to consumers more clearly that the current AUST L and AUST R labels.

Similarly, a permitted indications list should be developed and tested in consultation with consumer advocates and health experts to ensure that indications are clear, simple and are not easily confused by consumers.

[4] TGA Performance statistics report: https://www.tga.gov.au/book/export/html/731370

There should be significant consumer education and education of pharmacists on any new labelling introduced. Information should be made available instore, online and through health professionals to help raise consumer awareness of the scheme.

After new labelling is introduced, the TGA should periodically test consumer knowledge, perception and trust in the scheme and provide feedback to stakeholders on the success and concerns of its implementation.

Recommendations

- The TGA introduce the 'new pathway' for listed medicines allowing products to display a logo or tick after an independent assessment of their efficacy
- The TGA's assessment of evidence should be made publicly available
- Permitted indications must be simple and clearly labelled on products
- Permitted indications are thoroughly tested with consumers and health professionals
- Logo designs for the new pathway are thoroughly tested with consumers and health professionals
- The TGA should provide consumer and professional education through marketing and training on any new labelling introduced.
- Information about the pathway is made readily available to consumers and health professionals