[redacted]

Therapeutic Goods Administration: Reforms to the regulatory framework for complementary medicines.

Submission from PuraPharm Australia Pty Ltd

March 2017

Overview

PuraPharm Australia welcomes the opportunity to contribute to the Therapeutic Goods Administration's review and proposals for reform of regulations covering complementary medicines in Australia. PuraPharm strongly supports development of a regulatory framework which drives increases in the evidence base of complementary medicines, encourages innovation, and results in greater confidence on the part of health professionals and consumers in the impact, quality and safety of complementary medicines.

PuraPharm Corporation Ltd, the parent company of PuraPharm Australia, is one of the leading providers of granulated herbal medicines in China and Hong Kong. The company opened a business office in Australia in mid-2016.

1. New pathway for regulatory approval.

PuraPharm supports the proposal for a new pathway where solid scientific evidence of efficacy enables higher level of health claims to be made, and the hierarchy of evidence follows the medicine's risk profile. As a herbal medicine company with significant expertise in complex Chinese medicine formulae, we also support the proposal to move from published studies on separate ingredients to finished products.

Regarding the proposed approaches to establishing efficacy – we note that Method 1 requiring clinical data on the finished product that supports the specific indication, is the only option for herbal medicines. The challenge here is that although traditional medicines have been used for centuries, there is very little good quality clinical evidence for traditional herbal medicines and especially for the total formulae. Some of the currently available clinical data is very low quality, published in low level journals with low impact factors and citations.

For companies and researchers to obtain quality clinical data is time consuming and expensive.

PuraPharm Australia Pty Ltd
Level 4, 95 Pitt Street Sydney NSW 2000
[redacted]

PuraPharm invests heavily in clinical and basic research on individual herbs and formulae. As well as its own in-house research, PuraPharm funds programs in several universities in Australia and internationally. The timeline for each research project though runs over years and the budget for even a small Phase Ib trial (such as is being planned in Australia) is hundreds of thousands of dollars.

Under these circumstances, PuraPharm is keen to see further discussion on "approaches to establish efficacy". An approach which enabled traditional and modern herbal medicine companies to support their application with a suitable data package incorporating other factors including historical usage, would enable access to the new pathway while the global evidence base for traditional herbal medicines grows.

2. Claimers

PuraPharm agrees that providing a higher level of recognition to products which take the more difficult new pathway route is worthwhile.

One issue with the proposal for the TGA or other independent reviewer to support a claimer, such as those suggested in the document, is the variable quality of current research. To be meaningful, a statement such as "The efficacy of this product has been assessed" must incorporate some ranking of the quality of research, in much the same way as NHMRC assesses published research of academics. Unless this is done, consumers could be worse off believing that an unreliable/poorly constructed study is actually providing evidence – when it is doing no such thing.

It is my personal view that the community in general has a very low level of understanding of different regulatory pathways and categories of medicines, nor clear understanding of what the categories mean in terms of safety and efficacy. How many people understand, for example, the difference between pharmaceuticals v listed medicines v registered medicines v supplements and other unregulated products for sale in the local shop v medicines you can order online. For the community to make any real sense of claimers, requires a significant education program about medicine safety and what it means to establish efficacy.

Meanwhile, as the differences between listed, registered and the new pathway medicines are not widely understood (my personal view), a possible consequence of having what could be interpreted as government/TGA "endorsements" on some products, is a reduction in the standing of other "non-endorsed" complementary medicines. Under the circumstances, medicines that don't carry claimers ("not endorsed") could be seen in the marketplace with "not good" or "low quality" or similar rather than no evidence to support usage.

3. Innovation

PuraPharm strongly supports the market exclusivity period for new products or ingredients. Given the costs associated with obtaining laboratory and clinical data, and the time involved in applications and approvals, we would suggest extending the period for a new ingredient to three years, and to four years for new product. This is still well under the length of time that pharmaceutical companies have protected for their new drugs.

PuraPharm Australia Pty Ltd
Level 4, 95 Pitt Street Sydney NSW 2000
[redacted]

We are also strongly in favour of protection/exclusivity being available for new uses of existing products/substances. In traditional medicines, there are many examples of herbs used to treat multiple health conditions. Even where herb/s are approved ingredients, clinical data must be gathered for each of the conditions, and the cost of obtaining good clinical data is significant.

An exclusivity period for new ingredients and formulae, and for new uses, would encourage investment in research and gathering clinical data.

Conclusion

PuraPharm strongly endorses the objectives of the regulatory review. We would be very happy to participate in further discussions and contribute our expertise as a traditional herbal medicine company in any way which could assist, to achieve successful reform.

PuraPharm Australia Pty Ltd
Level 4, 95 Pitt Street Sydney NSW 2000
[redacted]