Dear Secretary,

I am writing to you regarding the Proposed Amendments to the Poisons Standard (Medicines/Chemicals) for the scheduling of cannabidiol outlined in the Public Notice of 17 April 2020.

BBS Pharmaceuticals was founded in South Australia in June 2017 and is an Australian medicinal cannabis company that holds two licenses under the Narcotic Drugs Act, 1967 (Cwlth) issued by the Australian Office of Drug Control; one in cultivation and one in manufacturing.

As a licence cultivator of medical cannabis and manufacturer of products containing medicinal cannabis, we are writing to support the proposed reforms.

We support better access for non psycho active medicines in general and believe that access from behind the counter via a pharmacist is a sensible approach.

Furthermore, this approach may help with the education of the wider community, regarding the benefits of CBD, and reduce confusion with respect to hemp seed oil, which some hemp producers promote and distribute as being CBD based in supermarkets.

In addition to the above, we strongly support the proposed amendment as it is a sales barrier to export CBD to international markets when Australia treats the products as Schedule 4 or 8 and for example the European Union treats it as a novel food. Hence, this amendment will provide a more even playing field for Australian cultivators and manufacturers.

Should this proposed regulation go through its various stages, become promulgated and hence come into operation either later this year or early next year, we will be able to respond with a regular and stable supply to meet the needs of the Australian domestic market through our capacity to grow and manufacture. Through our licensing, we have an obligation to ensure that we supply the domestic market as a priority. Our aim is to always proudly meet this obligation.

Suggested improvements:

We take this opportunity to express our concerns with respect to the inclusion of synthetic cannabinoids as there are still too many unanswered questions regarding synthetics. For example, synthetic opioids are still highly addictive despite claims made by some in the past. With naturally derived phyto-cannabinoids you know what you get and it's easily measurable.

We therefore suggest that point a. included in the proposed new entry in Schedule 3 be replaced with":

a. the cannabidiol is cannabis plant derived; and"

Furthermore, we request that the TGA through its various processes seek to clarify the difference between hemp grown for industrial purposes and cannabis grown for medical purposes. The reason being that producers of industrial hemp will attempt to supply non medicinal product into the market and measures should be put in place to prevent this from happening in order to protect the quality of product that goes into the manufacture of Schedule 3 products that can be detrimental to the health of consumers.

Finally, we have concerns in relation to the uneven playing field that exists between UN Convention on Narcotics, 1961 compliant countries such as Australia and non-compliant countries.

As a country compliant with the said Convention, Australia should reinforce its obligations by ensuring that product from non-compliant countries can not be imported into Australia. We believe that any permission granted by the Australian government or any of its agencies to allow product to be imported from countries that allow recreational use is in breach of the said Convention and such a decision is unconstitutional as it breaches our external treaty obligations.

Impacts:

In general, the impacts of the proposed amendments to Schedule 3 we believe will be positive for Australian cultivators and manufacturers including ourselves.

Our suggested improvements should not be seen as anti-competitive but rather necessary protections for the public ie. consumers and fairness and equity.

In terms of this proposed amendment, the most important objective is that the public will gain access to non-psychoactive medical cannabis products that can treat a range of indications without gridlocking the special access scheme with low risk requests. This is important as the liberalisation of CBD in Australia will hopefully result in greater demand for Schedule 3 CBD and hence the economies of scale should improve for cultivators and manufacturers alike. These improved economies of scale should deliver product to the consumer at a much more affordable price than at present.

AMA Submission:

We have noted comments attributed in the media to the Australian Medical Association (AMA) and in particular that they do not support this reform on the basis that it will "normalise cannabis use".

We are bemused by such an argument being put forward by the AMA. Their aim for a restricted approach where all cannabis products can only be prescribed by their members, is not supported.

Rather than adopting this approach, we believe the AMA could consider putting more resources into educating their members in terms of the proper prescription of Cannabis for a variety of indications.

Since the legalisation of medical cannabis, the AMA have had 3 years to do this. To the casual observer it appears that progress in this regard is slow.

Bearing in mind that there has been no known death across the globe from the ingestion of medical grade CBD, we see the 'behind the counter' approach as a sensible approach that pharmacists are more than competent to administer, by asking the appropriate questions.

We hope that this assists the committee with its important deliberations and hopefully we will see this promulgated either later this year or early next year.

Your sincerely

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www.bbspharmaceuticals.com