CHC industry estimation of costs associated with the implementation of the Guideline – Evidence required to support indications for listed medicines

Who will be affected? Are different groups in the community likely to be affected differently?	The introduction of the Evidence required to support indications for Listed medicines' guideline will significantly affect: **Australian consumer** – will ultimately pay more for the same product with no additional benefit, moreover, they would have less product choice. This proposal could be seen as anti-competitive on several grounds. The ill and those in lower socio-economic groups would be most disadvantaged. **Sponsors -** of listed goods will have greatly increased costs of compliance with the new guidelines to no effective net benefit in safety and quality to consumers.. Sponsors will have greatly increased timeframes to market new innovative products due to increased time to substantiate claims and the need for most to outsource this step as most CM companies would not have an 'expert' in house. **Manufacturers** – will have less products to make as sponsors rationalise ranges, and delete low volume turnover products when the regulatory costs are greater than sales of that product. **Retailers –** will have less product choice on the shelves as sponsors will find it cost prohibitive to launch innovative CM products with newer ingredients**.**
What will be the cost of the changes, can they be quantified?	It is difficult to quantify the unknown, many companies would not have the expert as defined in the document "in house" to write the expert reports, and an external consultant will be required to prepare the expert reports. The requirements for being qualified to prepare an expert report are quite similar for doing the same for a specialist prescription medicine. Based on feedback from companies the costs of having an expert report written (prescription), ranges between $10,000 - 25,000 AUD per report, depending on the length of the report and the time required to research and write the report. Other estimates based on updating current indications were around $800,000 based on the USFDA guidance for industry. [1] Estimates for companies with 500+ products could be as high as **approximately $1.3m plus for every company**.
How many products does your organization market?	Sponsors offer between 9 - 500+ products and small medium and large businesses have numerous products that would eligible for listing in the pipeline.
How many expert reports would need to be generated (per ingredient) ?	If the expert report is to be per ingredient, for every indication in every product:

[1] USFDA "Guidance for Industry: Substantiation for Dietary Supplement Claims".

	5- 10 claims per product was about average
Do you have this expert within your organization currently? If not, do you have an estimate of an hourly charge/total for completion of an expert report? (this will need to be justified if challenged)	The majority of members do not currently have the expertise as defined in the current document. Moreover, additional resource would be required to support the qualified personal. This proposal is highly prejudicial to small to medium businesses and could be seen as anti-competitive on several grounds. It also adds a significant barrier to entry in the terms of additional regulatory burden to all businesses in contrast to best practice regulation benchmarks. Estimate of an hourly charge were around $150 - 200+/hour based on consulting costs paid in the areas of GMP or Regulatory. Total estimates of cost of completion of a report in an appropriate format could be between $10,000 to $25,000 AUD.
Will the change impact consumers, commercial business, and competitive impact?	This will be an additional expense that is likely to be passed on to the consumer yet will offer no additional benefit to consumers in safety or quality. This could be expected to reduce investment in innovation, clinical trials and lessens incentive to launch products that are niche yet useful to consumers and therefore reduce consumer choice and healthcare options.
Would this make you remove any products from the market place y/n ?	The majority of members suggest that this is a certain possibility with some estimates of up to 20-30% of products currently marketed affected. If the increase in cost makes the product unprofitable, and there is no ethical obligation to keep the product on the market, then yes, products could be expected to be removed from the market as a direct result.
Would this make you convert your current medicines into foods to avoid these requirements?	The majority of members suggest this as a possibility that will be considered if the dosage form allows for it, especially given the pending proposal P293 published by FSANZ.
Does this impact on any products that you export?	Yes. If a product is deemed to be unprofitable in Australia due to the increased cost, it could be expected that the product is discontinued as export volumes are often less than domestic volumes and are generally very price/margin sensitive.
Could you estimate the overall impact: 1. % of products that are un likely to comply with new requirements 2. What this would mean in dollar terms	Commercially CM products are important and so companies will make sure that the products comply with the requirements – Albeit this will be at significant cost. Depending on the indication of the product, finding “experts” with the necessary qualifications and expertise required to prepare an expert report will be a challenge. One estimate based just on 9 listed products included on the ARTG, was that at least $90,000 AUD will be required just for authoring the reports. An estimate of approx. 45% of some company’s products (mainly

	herbal) would be deleted. Reducing overall $ sales of complementary medicines by %30 and reducing the effective forces of competition that have driven the Australian industry to be one of the most competitive global markets..
Any other feedback on additional costs of embedding the document into legislation Eg: using a librarian, accessing a minimum of 2 databases for the literature search, Obtaining an independent review (in addition to expert) if any unpublished studies	The proposal really is a paradigm shift in the way evidence to support claims and indications are supported for listed medicines and the cost of research will be prohibitive. This may lead to a larger amount of products to be purchased overseas via the internet, if products become unavailable in Australia. Companies may also setup offshore to facilitate this method of purchase. This movement is likely to delay Trans-Tasman harmonization due to what will be the worlds strictest low risk medicine regulation compliance requirements in Australia. Additional ancillary services may be required, such as legal teams for preparing contracts, and compliance officers ensuring the consultants comply with the anti bribery and corruption Act will also need to be engaged. Costs for librarian and databases are additional as well. Costs associated with this could be up to $2,000 per report.