

From: info@safflower.com.au
To: [GMP](#)
Subject: Fees and charges consultation feedback [SEC=No Protective Marking]
Date: Friday, 23 February 2018 12:03:52 PM

Dear Sir/Madam,

Thank you for providing us with the opportunity to give feedback to the proposed three options outlined in your GMP fee model review:

Firstly, we would like to question if there have been any internal audits into budgets and revenue spending by the department of Health? Also, if there has been any internal cost analysis taken place? Asking for more revenue from a small business like ours to cover your department's loss of revenue issues severely impacts our business. Establishing and maintaining GMP compliance has been a huge undertaking for our small business which tremendous impact on our bottom line. The costs of staff hours addressing this framework as well as the annual fees and charges cut deeply into our profit margin. Any increase in these charges could seriously jeopardise this company's future.

Regarding the 3 options outlined:

Option 1: this would be far too costly for us to add another large expense by increasing charges in low level manufacturing, inspection fees, processing fees, compliance fees etc. This option would add thousands of dollars onto our annual budget.

Option 2: While option 2 doesn't add costs onto our annual budget, it would add an approximate \$7000 on our 3-yearly inspection fee. This increase would be unrealistic to a small company like ours, which is already struggling to comply with the current inspection rate.

Option 3: This option does provide us with a less annual manufacturing charge but is disproportionate in the fact that small manufactures like us, are charged the same as large companies. Secondly, by significantly increasing the hourly inspection rate, we would be looking at a \$6000 increase. For a small business to budget for such a large increase of capital is extremely difficult and untenable.

In summary, we would suggest that these 3 options are untenable for a compounding facility like ours. We work diligently and efficiently to abide by high GMP industry standards.

We understand the need and believe in the principles that the TGA stands for. Like any company we acknowledge that to grow we need to provide a commitment of excellence and that being member of the GMP provides that platform. But to grow as a company we need to budget and improve our cash flow. To be asked to finance the revenue disparities of the Department of Health, through these 3 proposals inhibits our chance to grow into a more substantial company. I would strongly suggest that internal costs and budgets are analysed in your department and a greater consideration of small businesses charges kept more proportionate to that of larger manufacturing companies. We hence suggest that the TGA investigates a fee model that is based on an operator's revenue. The other option would be to establish a pool of GMP TGA members and finance the inspections

from that money.

Best wishes & kind regards,

Brigitte Linder

Chinese Medicine Practitioner / QA Manager

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