Australia New Zealand
Industrial Gas Association

5 March 2018

Ben Noyen
Assistant Secretary
Manufacturing Quality Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
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Dear Ben,

Consultation: Proposal to change the current good manufacturing practice (GMP) fees and charges.

The Australia New Zealand Industrial Gas Association (ANZIGA) is the peak industry association representing companies that produce and distribute industrial gases, including bulk and compressed gas for the industrial, medical, food, scientific and hospitality markets (referred as Industrial Gases) in Australia and New Zealand.

Industrial, food and medical gases are essential to the existence and wellbeing of hundreds of thousands of people, every day. Lifesaving, life enhancing or life promoting, compressed and bulk industrial gases underpin the technologies that keep us connected and informed, and the lifestyle we desire.

They support Australia's manufacturing, refining, welding, chemical processing and electronics sectors. They also ensure that our food is nutritious, appealing and affordable and that our water is clean. Medical gases are important to the health and wellbeing of many, and essential in many medical procedures and equipment.

The industrial gases sector, and the industrial and medical gases companies it represents, are an important enabler for many strategic industry sectors that support the Australian economy.

ANZIGA appreciates the opportunity to comment on the proposal to change the current good manufacturing practice (GMP) fees and charges, and the consultation paper prepared by Deloitte.

ANZIGA members believe that the proposed changes to the GMP fees represent significant changes that companies need to be able to review prior to implementation. Companies require some surety in budgeting and at this late stage in the financial year they have not had the opportunity to plan for this change. ANZIGA would propose that any change in fees must not be implemented until 2019 to allow all budgeting requirements to be fulfilled.

The changes to fees all incorporate a defined hourly rate for inspections and audits. ANZIGA believes, again to allow some surety of budgets, that audit schedules must be predetermined in advance, in consultation with the company, and that this schedule is adhered to strictly. Unexpected or unwarranted audits should not occur, unless there are critical compliance issues. The length and time of audits must also be closely monitored to ensure that the costs are minimised and the ability to raise revenue is not abused.

ANZIGA has previously made a submission in March 2018 to TGA in relation to the Draft Licencing and Certification Guidance. This issue is relevant to the cost recovery in relation to GMP variation fee.

ANZIGA's comments related to notification to the TGA of changes to nominated persons responsible for production and quality. The issue relates to the relative high frequency that the medical gas manufacturers are required to issue GMP manufacturing licence variation applications for the change of nominated persons responsible for production and quality. This is due to the large number of manufacturing sites that ANZIGA members collectively operate. Given average staff turnover, the large number of manufacturing sites makes this notification requirement relatively frequent which adds non-value added administrative work, and as outlined in this current consultation paper, now potentially a substantial variation fee.

At this stage ANZIGA is not aware of the outcome of the above review, but if this proposal is accepted by TGA, it will reduce the cost burden on industry.

If any further information and comment is required, please do not hesitate to contact me.

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