5 March 2018

Medicines Scheduling Secretariat
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
Australia

RE: Consultation: Proposed amendments to the Poisons Standard – ACCS, ACMS and Joint ACCS/ACMS meetings, November 2017
Comments on the request for changes to the scheduling of Ibuprofen

Dear Sir/Madam,

We welcome the opportunity to comment on the consultation regarding fees related to GMP applications. We note that the cost-recovery of activities related to GMP activities has been negative in the past four years and prompts this discussion about under recovery. We acknowledge the difficulties encountered and also note that he TGA has instituted changes in some aspects of the GMP evaluation process in late 2017 to improve efficiencies in evaluating desk-top and MRA evaluations. It is unlikely that the outcome of these changes has been factored into this assessment of the under recovery of fees and therefore trust that further evaluation of the fees structure will occur in the following years to determine whether any efficiencies have been attained from such changes.

With regard to the proposals outlined in the consultation document, we are happy to support the Option 3 proposal.

Nova is a small size local sponsor of OTC and complementary medicine products and uses manufacturing sites in Asia, Europe and USA. There are a small number of manufacturing sites that are used and all have the potential for on-site inspections or GMP clearances would be relying on desk-top audits. Hence, the impact of Option 3 would be to increase the cost of applying for a desk-top audit or MRA submission but would not change the current fee structure for overseas inspections. As we do not have local manufacturing, any changes to the fee structure in this sector does not have any direct impact on costs (there may be an indirect cost where local manufacturing sites are used for some products). Due to the smaller number of manufacturing sites used to support the business, the impact would be an increase of a few thousand dollars spread over a rolling three-year period (noting that GMP inspections for any site generally have a 3-year expiry before re-inspection).

Just to provide comments on the other two options proposed. We would disagree with Option 1 to have a general across the board increase to cover the short fall as this does not address any underlying causes of the under recovery and any solution should be trying to account for changes made by the TGA for improve efficiencies. As a small local sponsor this would result in a significant increase in cost and would not provide

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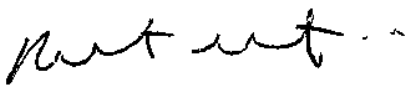
any change in the level of service offered currently and we would be subsidising activities unrelated to the business.

Regarding Option 2, this addresses the specific issues of the under recovery relating to the local inspections but addressing only this aspect may be discouraging for local manufacturers. The impact for our company would be the increase in the hourly rate for overseas inspections due to the potential that we have sites that may be inspected by the TGA and hence this would result in higher fees for the inspection. As noted in the report, the TGA tends to recovery the costs of overseas inspections through charging all relevant costs and hence would not be supportive of additional increases to meet the TGA under recovery.

Therefore in conclusion, we are happy to support Option 3.

Should you require further information please do not hesitate to contact me at the contact details listed below.

Yours sincerely,
NOVA PHARMACEUTICALS AUSTRALASIA PTY LTD



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