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Regulatory Integrity Section
Office of Corporate Services
Therapeutic Goods Administration
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Consultation: Review of the Low Value Turnover Exemption Scheme

GlaxoSmithKline (GSK) welcomes the opportunity to comment on the consultation paper *Review of the Low Value Turnover Exemption Scheme.*

GSK is a global research-based healthcare company operating in more than 100 countries around the world. Our mission is to improve the quality of human life by enabling people to do more, feel better and live longer.

In Australia we have improved people's wellbeing by delivering the highest quality medicines, vaccines and over-the-counter healthcare products since the early 1900s. In Australia, GSK is present and recognised by the Therapeutic Goods Administration (TGA) as two separate sponsors: firstly, GlaxoSmithKline Australia Pty Ltd which represents our pharmaceuticals business and GlaxoSmithKline Australia Pty Ltd Consumer Healthcare Division which represents our consumer healthcare business.

This submission represents the views of both GSK's pharmaceutical and consumer healthcare businesses.

GSK agrees that the current low value turnover (LVT) exemption scheme is administratively complex for both sponsors and the TGA. The particular challenges which GSK recognises is that it can be complex and time-consuming to match the turnover of particular product presentations against individual ARTG numbers. In GSK each pack size is tracked and managed individually, whereas an ARTG number can represent various different pack sizes of the product. GSK also believes that the third party certification for reported turnover is an unnecessary compliance step which adds additional administrative work and costs to the process. GSK therefore welcomes any opportunities in which the scheme can be simplified to reduce the administrative burden.

In spite of the complexity of the process in preparing an LVT application, GSK can confirm that it currently utilises the LVT exemption scheme for GSK's prescription medicines portfolio within its pharmaceutical business. GSK realises financial benefit from the scheme which allows GSK to operate more efficiently and direct resources to regulatory activities required for those products which are supplied to the Australian market.

Overall, GSK is mainly supportive towards Option 3: *Replace the LVT scheme with one that only grants exemptions for Register entries not supplied to the Australian market*. Consistent with the Government's deregulation agenda, this option represents a meaningful reduction in the administrative burden for sponsors. GSK believes that this option may be a feasible way forward to simplify the criteria for eligibility and improve the efficiency of the scheme. Option 3 is justified since only therapeutic goods which require

post-marketing monitoring and regulation will be required to pay annual fees. This option also allows sponsors to retain products on the ARTG until a time that there is a new viable opportunity to recommence supply (e.g. after modifications to the product or a change in the external environment). In genuine cases where products have low commercial value but it is medically-critical to maintain supply, then the TGA can take action to consider these products on a case by case basis.

Acceptability of Option 3 comes with the expectation by GSK that annual fees for supplied goods would commensurately be reduced on the expectation that a broader range of ARTG entries will become eligible for annual fees. In addition, GSK suggests that third party certification would not be required and that a declaration by a suitably qualified employee of the sponsor would suffice. GSK would welcome further details on how the TGA propose to implement this option.

A variation of Option 3 proposed by the TGA is to remove the LVT exemption scheme but to charge lower annual fees for products which are not supplied. GSK is unable to comment on this option as no information is provided as to what these charges would be or how they would be calculated.

GSK is not supportive of ceasing the scheme (Option 5 in the consultation document) or restricting eligibility to small businesses only (Option 4 in the consultation document) and notes that both of these options are inconsistent with cost recovery principles.

GSK welcomes the opportunity to make this submission and looks forward to reviewing the outcomes of this consultation.

If you require any further information from GSK Australia, or if we can be of any assistance, please do not hesitate to contact by e-mail at or phone on .

Yours sincerely,

GlaxoSmithKline Australia Pty Ltd