

Submission No. 41



23 May 2014

Regulatory Integrity Section
Office of Corporate Services
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
Email: lvtconsultation@tga.gov.au

Dear Sir or Madam

Re: Review of the low value turnover exemption scheme

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As the world's biggest biotech company and an innovator of products and services for the early detection, prevention, diagnosis and treatment of diseases, the Group contributes on a broad range of fronts to improving people's health and quality of life.

Roche Products Pty Limited (Roche Australia) is the Australian Head Office for the Pharmaceutical division of Roche Australia.

Roche Australia currently has 121 products registered on the Australian Register of Therapeutic Goods, of which a substantial proportion are prescription biotechnology products. These products are maintained on the register at a cost of over half a million dollars annually. Roche Australia benefits little from the LVT exemption as those products qualifying for exemptions tend to be in their launch year, when sales are low. Roche Australia does not in general register products which are not subsequently marketed.

It is Roche Australia's view that the cost of post-marketing regulatory maintenance of products should be borne by the sponsor of the product on the market as a routine cost of business. Roche Australia does not agree with this cost being distributed to other sponsors, particularly as the LVT initiative no longer serves the purpose for which it was created.

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Therefore, of the options presented in the TGA's consultation document "Consultation: review of the low value turnover exemption scheme", Roche Australia supports Option 5, to cease the LVT completely.

Sincerely,

Roche Products Pty Limited