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24 February 2006

Regulation Review
Independent Pricing and Regulatory Tribunal
PO Box Q290
QVB Post Office NSW 1230

Dear Sir/Madam

GlaxoSmithKline (GSK) welcomes the opportunity to contribute to the IPART Investigation into the burden of regulation in NSW and improving regulatory efficiency.

GSK is a world leading, research-based pharmaceutical company dedicated to meeting the healthcare needs of people around the world and helping them do more, feel better and live longer. The company is a global leader in the research, development, manufacture and supply of prescription medicines, vaccines, over the counter medicines, oral care products and nutritional healthcare drinks. It has a strong presence in Australia with operations in all states and major production facilities at Ermington (NSW) as well as Boronia, Latrobe and Port Fairy (Victoria) employing more than 1,500 Australians.

GSK supports the NSW Government's desire to improve the efficiency of regulation through identification of priority areas where regulation is imposing an unnecessary burden on business and the community and where there are good prospects of regulatory reform.

The Issues Paper[1] noted that there has been a growth in the regulatory burden, which may impact on the ability of business to conduct their operations in the most efficient manner possible. While regulation plays an important role in ensuring that markets can operate in an efficient, effective and predictable manner; over-regulation, or regulation of the wrong type can distort decision-making and impose unnecessary costs of business, Government and the community.

A major area of concern in the regulatory arena for GSK (operating in all States and Territories) is national consistency. In some circumstances, it may be appropriate for States and Territories to adopt different legislation and regulation to suit unique circumstances within their jurisdiction. However, in the area of regulation of pharmaceuticals (whether it be labelling, Medical samples or storage and handling), there is no compelling justification as to why States and Territories should retain inconsistent regulation which, in some circumstances, is incompatible with Commonwealth legislation.

In 2001, the final report of the National Competition Policy Review of Drugs, Poisons and Controlled Substances legislation (the Galbally Review), was presented to the Australian

[1] Independent Pricing and Regulatory Tribunal of New South Wales, Investigation into the burden of regulation in NSW and improving regulatory efficiency, www.ipart.nsw.gov.au, January 2006

Health Ministers' Advisory Council (AHMAC). The latter formed a working party whose role was to prepare comments on the report for the Council of Australian Governments (COAG). In June 2005, the recommendations of the Galbally Review and the AHMAC working party response were agreed by COAG.

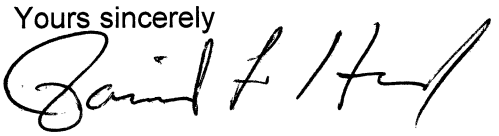
GSK understands that the delay in implementing the recommendations of the Galbally Review needs stems, in part, from a need to harmonise with the implementation of the new Australia New Zealand Therapeutic Products Authority. While GSK recognises that many of the recommendations require legislative change, which could be efficiently implemented with the necessary legislative amendments arising from the new agency, the recommendations that harmonise State and Territory arrangements, should not require further delay, and should be implemented as a matter of priority.

The Galbally Review noted that national inconsistency in the regulation on drugs, poisons and controlled substances imposed avoidable costs on businesses. In the area of medical samples (packets of medicinal product, often in a smaller quantity, distributed to a health professional for the purpose of promoting and educating around the use of a new product), inconsistency between States and Territories in regulation of Medical samples imposes significant burdens on business, both through the nature of the restrictions themselves (which often place overly burden on business conduct such prospective prohibition), and the inconsistency between jurisdictions. For a company such as GSK, operating within all eight jurisdictions, compliance with the different regulations imposes impediments on the operation of our business.

The recommendation of the Galbally Review was that State and Territory regulation relating to the provision of clinical samples be repealed. It was determined that amendments to the Australian Pharmaceutical Manufacturers Association (now Medicines Australia) Code of Conduct (underpinned by legislation) would provide a more efficient means of regulating the supply of medical samples, whilst still ensuring that the objectives of the legislation are being met. It was proposed to amend State and Territory legislation to ensure that it is a condition of licensing for manufacturers and wholesalers that they comply with Medicines Australia Code of Conduct for the Supply of Medical Samples. This model of co-regulation has proven to be very successful for regulation of the medicines industry, and should be used as a means of ensuring the objectives of regulation are achieved in an efficient and effective manner.

I would be happy to meet with the convenors of IPART's review to discuss GSK's position on this matter. I can be reached on (03) 9721 8722. Once again, thank you for the opportunity to comment on this important matter.

Yours sincerely



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