19 April 2013





Dear Sir/Madam

Submission regarding the Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill

Merck Sharp & Dohme (Australia) Pty Ltd's ("**MSD**") would like to provide a submission regarding the Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill. MSD supports Medicines Australia Limited's ("**Medicines Australia**") recently reauthorised Code of Conduct ("**Code**").

MSD believes the underlying policy objectives of this Bill are best achieved through the Code and the policy development work of the recently established Medicines Australia, Transparency Working Group. If the Senate Committee is genuine about maintaining the integrity of the health system and safeguarding patient confidence in health care professionals, it should support the Transparency Working Group completing its work.

MSD is a leader in the Australian innovator pharmaceutical industry. Our products cover a broad range of areas, including heart and respiratory health, infectious diseases and women's health. We focus our research on conditions that affect millions of Australians – diseases like osteoporosis, cardiovascular, diabetes and cancer.

The most significant change recently introduced by Edition 17 of the Medicines Australia Code of Conduct, is the requirement for member companies, such as MSD, to provide public disclosure of aggregate payments to doctors and consumer groups. MSD supports this substantial change to the Code and the operation of the innovator pharmaceutical industry in Australia. MSD believes that this change to the Code represents a significant shift towards greater transparency by the innovator pharmaceutical industry and will go a long way to build trust and public confidence in our industry and MA member companies.

Although interactions between pharmaceutical companies and health care professionals should be subject to transparency mechanisms and industry regulation, it is important to acknowledge that certain interactions are appropriate and indeed necessary to ensure patients have optimal access to new medicines. This Bill seeks to ban sponsorship of activities that are important to industry-doctor interaction, the capabilities of Australian doctors and, ultimately, the welfare of Australian patients.

In order to implement such unprecedented business disclosure, MSD and other MA member companies must implement a process that involves many different stakeholders, not just innovator pharmaceutical companies such as MSD. It also involves medical professionals, consumer health bodies, the broader public, and those pharmaceutical companies who are not members of MA.

MSD believe that as a result of Edition 17 of the Code, the innovator pharmaceutical industry is now setting a higher standard of transparency in its interactions with medical professional, while allowing the multiple stakeholders involved the opportunity to address the issues associated with, and adjust to, such disclosure. MSD considers that such issues include privacy and consent to future individual disclosure.

Aggregate level disclosure is a responsible first step which supports the transition to greater disclosure.

MA reached an agreement with the ACCC to establish the Medicines Australia Transparency Working Group. This Working Group includes members from across industry, consumer representatives and healthcare professionals.

The Transparency Working Group is tasked with delivering the desired outcome of transparency and disclosure in an efficient manner. Its process will seek a consensus across stakeholders and with due regard to the privacy interests of doctors and their patients.

MSD supports the work of the MA Transparency Working Group and we strongly believe that the Group needs to complete its review and consultations in order to put appropriate processes in place for full disclosure. We believe this process must continue and not be interrupted by rushed-through legislation.

Because millions of people in Australia and around the world depend on our products, we are committed to the highest standards of ethics and integrity in how we conduct ourselves as a company. MSD acknowledges that our integrity and credibility is an enabler in building trust with consumers and health care professionals. We believe the Medicine Australia Code of Conduct (Edition 17) which requires MSD and all other member companies to publicly disclose aggregate payments to doctors and consumers is consistent with emerging community expectations for our industry.

The Bill should be opposed and not passed by the Senate.

Yours faithfully

Dr Susanne Fiedler Managing Director Australia & New Zealand

Merck/MSD is a global healthcare company and is known Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and consumer care and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit http://www.merck.com and connect with us on Twitter, Facebook and YouTube.