

MSD

Merck Sharp & Dohme (Australia) Pty Limited
ABN: 14 000 173 508
Level 1 - Building A, 26 Talavera Road
Macquarie Park NSW 2113
North Ryde Post Business Centre
Locked Bag 2234 North Ryde, NSW, 1670
T 02 8988 8000
F 02 8988 8001
msd-australia.com.au



Committee Secretary
Senate Economics References Committee
PO Box 6100
Parliament House
Canberra ACT 2600

16th July 2015

Dear Dr. Dermody,

Please see enclosed our responses to questions taken on notice during the 1 July inquiry into corporate tax avoidance.

Yours Faithfully

Paul Dodd
Finance Director

1. Response to a Question on Notice from the Hon. Senator Milne to all companies

[As reported in Hansard on 1 July 2015] Senator Milne: *"So could I ask you, on notice: for the past 10 years of annual financial reports for the committee so that we are in a position to analyse those."*

Response

Merck Sharp & Dohme (Australia) Pty Limited is a member of a Consolidated Tax Group comprising a number of entities. Each entity within this group produces its own Statutory Financial Statements.

The table below provides a summary of the entities comprising the Tax Consolidated Group.

Entity	Status	Year Joined Consolidated Tax Group
Merck Sharp & Dohme (Australia) Pty Ltd	Human health trading company	1/7/2011
Merck Sharp & Dohme (Holdings) Pty Ltd (Formerly Schering-Plough Pty Limited)	Human health holding company	19/11/2008
Intervet Australia Pty Limited	Animal health trading Company	5/9/2009
Intervet Schering-Plough Animal Health Pty Limited	Animal health holding company	19/11/2008
Livestock Nutrition Technologies Pty Limited	Dormant Entity	5/9/2009
Intervet Rural Co. Pty Limited	Dormant Entity	5/9/2009

We have provided Statutory Financial Statements for Merck Sharp & Dohme (Australia) Pty Ltd (refer to Appendix One), given this was the entity specifically referred to in the senate inquiry and for which financial information was quoted by the senate committee. We are happy to provide Statutory Financial Statements for any other entity in the group upon request.

Merck Sharp & Dohme (Australia) Pty Ltd will be referred to as MSDA in the remainder of the response.

2. Response to a Question on Notice from the Hon. Senator Milne to all companies

[As reported in Hansard on 1 July 2015] Senator Milne: *"As Senator Xenophon is saying, we want comparative actual prices that you pay for the drugs in each similar jurisdiction—that is, if it is a predominantly distributor jurisdiction, what is the price you pay for the same drug in different countries that are also in distribution? The second thing is you have said that that price is determined by the profitability formula. What I am interested in is what profitability formula is applied".*

Response

MSD applies a consistent transfer pricing methodology, taking into account the assets, risks, functions and activities of each affiliate. These methodologies follow the international standards for the arm's length principle developed by the Organisation for Economic Co-operation and Development ("OECD") and are also embedded in the Australian tax legislation.

There are a number of transfer pricing methods that can be applied in accordance with this arm's length principle, which are detailed in Appendix Two. The Transactional Net Margin Method is considered the most appropriate method for MSDA. This method benchmarks operating margin (net profit / sales) against independent comparable companies performing similar purchase and distribution activities and bearing similar risks to MSDA. This annual benchmarking exercise is completed with support of a third party service provider.

Transfer Price

The transfer prices of individual products are calculated, but not benchmarked for their at arm's length nature, since this is not relevant under this transfer pricing method. Instead, the transfer price of a specific product is calculated to ensure that the affiliate will realize an arm's length operating margin.

In establishing transfer prices, all operating expenses of MSDA relating to the distribution and marketing are taken into account, including an appropriate allocation of overhead costs. In more detail, these costs include warehousing and distribution costs, discards, marketing costs, employee costs, overhead etc. as outlined in the following summarized example.

Revenue	AUD	10,000
Costs of goods	AUD	Xxx
Gross Profit	AUD	3,500
Operating expenses	AUD	(3,000)
Operating Profit	AUD	500
Operating margin	AUD	5%

Assuming that in this example the 5% operating margin is benchmarked to be at arm's length, the required operating profit of 500 is known (5% of 10,000). Adding back the operating expenses of 3,000 we can then calculate the required gross profit as 3,500. The cost of goods (transfer price) can then be calculated and should amount to AUD 6,500 to ensure that the arm's length operating profit and operating margin is achieved.

Comparability with other overseas MSD entities

MSD applies a consistent transfer pricing methodology for its overseas affiliates, taking into account the assets, risks, functions and activities for each affiliate.

This does not necessarily mean that the operating margins of overseas MSD entities acting as a distributor are identical to the margins of MSDA. There can be various reasons causing deviations between an overseas affiliates operating margin compared to MSDA's operating margin:

- Where an overseas affiliate hold different assets, risks, functions and activities which therefore drives a higher or lower arm's length margin
- Where an overseas affiliate hold the same level of assets, risks, functions and activities, but local benchmarking against independent comparable companies gives a different arm's length range in that jurisdiction

Also, the transfer prices may not be identical among all MSD Affiliates even if operating margin is the same, given the transfer pricing method adopted. Many factors may cause the transfer prices of an individual product to be different compared to the transfer price to MSDA for such product:

- Where selling price varies by country. It could be higher or lower than MSDA.
- Where operating expenses vary, due to cost differentials in that jurisdiction, market strategy, selling models, foreign exchange and many other factors.

The following example may clarify that although the transfer price for individual products may differ, that the operating margin, is still at arm's length in either one of the scenarios.

		Country A	Country B	Country C
Revenue	AUD	10,000	12,000	10,000
Costs of goods	AUD	(7,000)	(8,900)	(6,000)
Gross Profit	AUD	3,000	3,100	4,000
Operating expenses	AUD	(2,500)	(2,500)	(3,500)
Operating Profit	AUD	500	600	500
Operating margin	AUD	5%	5%	5%

Summary

In light of the above, it should be noted that the transfer price itself is therefore not deemed a relevant comparator under these transfer pricing principles.

MSDA uses recommended and well recognised OECD transfer pricing methodology to ensure its transfer prices are consistent with the arm's length principle set out in the OECD Guidelines and embodied in Australia's domestic and international tax agreements.

Appendix Two

OECD Transfer Pricing Guidelines

Merck & Co., Inc.'s international companies, including MSDA, follow the international standards for the arm's length principle developed by the Organisation for Economic Co-operation and Development ("OECD"). The OECD has published extensive guidelines with respect to transfer pricing and the arm's length principle; the Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations (hereafter the "TPG"). The original versions dates from 1995 and it has been revised and updated several times, the last time in 2010. The TPG are incorporated by reference into the commentary to article 9 of the OECD Model Tax Convention.

Chapter II of the TPG contains a discussion of five transfer pricing methods that can be applied to establish whether the conditions of controlled transactions are consistent with the arm's length principle. These five methods consist in three "traditional transaction methods": the comparable uncontrolled price method ("CUP" method), the resale price method, and the cost plus method; and two "transactional profit methods": the transactional net margin method ("TNMM") and the transactional profit split method.

MSDA and its advisors have determined that TNMM is the most appropriate method to analyse MSDA's profitability in the intercompany transactions related to purchase and distribution of pharmaceutical products. Therefore, it adheres to these guidelines from the OECD which have been adopted in Australia's tax legislation.

The Transactional Net Margin Method (see below extract from TPG paragraphs 2.58-2.107)

14. The transactional net margin method ("TNMM") examines a net profit indicator, *i.e.* a ratio of net profit relative to an appropriate base (*e.g.* costs, sales, assets), that a taxpayer realises from a controlled transaction (or from transactions that are appropriate to aggregate) with the net profit earned in comparable uncontrolled transactions. The arm's length net profit indicator of the taxpayer from the controlled transaction(s) may be determined by reference to the net profit indicator that the same taxpayer earns in comparable uncontrolled transactions (internal comparables), or by reference to the net profit indicator earned in comparable transactions by an independent enterprise (external comparables).

15. In cases where the net profit is weighed to costs or sales, the TNMM compares **the net profit** arising from controlled and uncontrolled transactions (after relevant operating expenses have been deducted) instead of comparing a gross profit on resale or gross mark up on costs.

16. Most often, the net profit indicator that is tested in a TNMM is the operating profit (before interest, extraordinary items and income taxes).

17. In general, it is observed that in applying a TNMM, the net profit is weighted to costs for manufacturing and service activities; to sales for sales activities; and to assets for asset-intensive activities.

MSD Australia

Generally for distributors, the appropriate profit indicator is Operating Margin, expressing operating profit as a percentage of sales. This profit level indicator is also applied by MSDA for its sales and distributor activities of pharmaceutical products.

3. Response to a Question on Notice from the Hon. Senator Milne to MSD Australia on 1 July 2015

Claims in relation to Vioxx

[As reported in Hansard on 1 July 2015] Senator Milne: *"Can I ask MSD: can you confirm that the company has been involved in criminal prosecution in relation to a painkilling drug, Vioxx, for example, which I understand contributed to between 88,000 and 140,000 heart attacks, half of them fatal, and that the settlement you reached of \$950 million did not include the hundreds of millions that you had to pay out to harmed patients and their families. Can you tell me where that is up to?I am particularly interested in the Australian payouts in relation to the misuse of that particular drug."*

Response

MSD Australia offers the following response to the Honourable Senator's questions in relation to Vioxx:

MSD Australia, its parent, Merck & Co, Inc., and their affiliates (**Merck**) continue to believe that Merck behaved responsibly every step of the way concerning the safety profile of Vioxx, including voluntary withdrawal of the product from the worldwide market on 30 September 2004.

United States

In the United States, in November 2011, Merck resolved an investigation by the US Federal and State governments concerning Vioxx. As part of the resolution, Merck entered into civil settlement agreements with those governments which did not include any admission of wrongdoing by Merck.

Separately, the company agreed to plead guilty to a misdemeanor under the US Federal *Food, Drug & Cosmetic Act* arising out of the marketing of Vioxx by company representatives to doctors in the United States for the treatment of rheumatoid arthritis before the US Food and Drug Administration's approval of that indication in April 2002.

As for civil lawsuits, Merck won the vast majority of the cases that went to trial in the US, and thousands of other cases were dismissed before trial when investigation revealed them to be without merit. In November 2007, for pragmatic business reasons related to the litigation environment in the US, Merck commercially resolved the US litigation.

Merck respectfully believes that the heart attack numbers referred to by the Honourable Senator do not accord with relevant medical science or any legal determination of that proposition. Indeed, recent analyses have supported the conclusion that the cardiovascular profile of Vioxx is in fact no different from that of many other pain relievers that remain on the market throughout the world.

Australia

Australian claims in relation to Vioxx were finalised in a single representative proceeding (class action) under Part IVA of the *Federal Court of Australia Act 1976* (Cth). Commenced in 2005, Mr Graeme Robert Peterson brought the action on his own behalf and, through consolidation of earlier claims, on behalf of all Australian Vioxx claimants. He was represented by Slater + Gordon. MSD Australia and Merck & Co, Inc. were named as Respondents.

Mr Peterson's claim and common issues were tried in 2009. Those allegations are now the subject of judgments at first instance (Jessup J) (2010) and by a Full Federal Court (Keane CJ (as he then was), Bennett J and Gordon J (as she then was)) (2011). In 2012, the High Court (French CJ and Crennan J) refused Mr Peterson's application for special leave. As a consequence of those judgments, Mr Peterson's personal claim was dismissed, the action against Merck was dismissed and various alleged causes of action were dismissed. There were orders against Mr Peterson as to the Respondents' costs at each level.

On 26 February 2015, the Federal Court of Australia exercised its power under s33V of the *Federal Court of Australia 1976* (Cth) to make orders dismissing the Australian Vioxx litigation in its entirety. In doing so the Court approved a plan under which 259 individuals who had met specified criteria qualified to receive a pre-determined amount towards their personal expenses from a fixed pool of just under A\$545,000. Mr Peterson's application for approval was by consent with the interests of group members represented by Senior Counsel appearing as *amicus curiae*. Consistent with the prior judgments of the Court, the resolution was approved absent any admission of liability by or obligation upon MSD Australia or its related entities.