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Dear Interested Party

### **Proposed merger between Schering-Plough Corporation and Merck and Co. Inc – effect on human health markets**

The Australian Competition and Consumer Commission (ACCC) has been advised of the proposed merger by Schering-Plough Corporation (**Schering-Plough**) and Merck and Co. Inc (**Merck**) (the **proposed merger**). Schering-Plough and Merck are involved in research and development, manufacturing and marketing of human and animal health products.

The ACCC is currently considering the proposed merger under section 50 of the *Trade Practices Act 1974* (**the Act**). Section 50 of the Act prohibits mergers and acquisitions that substantially lessen competition in a market, or are likely to do so.

The ACCC invites your comment on the competitive effects of the proposed merger, specifically relating to human health products.

The ACCC is also seeking submissions on the competitive effects of the merger as they relate to animal health products. To make a submission in relation to animal health products, please contact Ms Sheridan Burnett on (02) 6243 1296.

The ACCC will also be conducting a review of Pfizer Inc's (**Pfizer**) proposed acquisition of Wyeth Corp (**Wyeth**). The ACCC has received a partial submission from Pfizer and will wait to receive a full submission before commencing its review of the proposed acquisition. The ACCC will also be seeking submissions on the competitive effects of Pfizer's proposed acquisition of Wyeth.

### **Background**

Schering-Plough is a global research and development company that produces prescription pharmaceuticals, animal health and consumer health care products. Schering-Plough's prescription pharmaceuticals business covers the following areas: allergy and respiratory, arthritis, immunology, cancer therapies, cholesterol/cardiovascular, cold and flu, dermatological and skin disorders, infectious diseases, hormone therapies and the central nervous system. Schering-Plough supplies over-the-counter (OTC) cold and flu products, OTC allergy and respiratory products, foot care products and sun care products through its consumer health care business.

Merck is a global research pharmaceutical company that discovers, develops, manufactures and markets a broad range of health products. Merck's operations comprise two main human health segments: pharmaceuticals and vaccines. Merck manufactures and distributes prescription pharmaceuticals for the following areas: cholesterol, anti-fungals, osteoporosis,

Parkinson's disease, migraine, arthritis, asthma, diabetes, hypertension (high blood pressure) and HIV/AIDS.

In relation to human health, Merck and Schering-Plough overlap in the areas of allergic rhinitis treatments, anti-fungal treatments, lipid management, hypertension treatments and arthritis treatments.

Merck and Schering-Plough are also involved in research and development activities, with a number of products in the pipeline. If pipeline products in phase three clinical trials are included, Merck and Schering Plough also possibly overlap in the therapeutic areas of HIV/AIDS, asthma and sarcoma.

### **Request for submissions**

The ACCC is conducting market inquiries to assist with its review of the proposed merger and would welcome any comments that you have in relation to the competitive effects of the proposed merger, specifically in relation to human health products. The specific issues on which we would appreciate your response are outlined in **Attachment A**. We recognise that you may not be able to comment on all of the issues raised but any assistance that you could provide would be greatly appreciated.

If the information provided is of a confidential nature, you can be assured that the details provided by you will be treated confidentially. That is, the ACCC will not disclose the confidential information to the merger parties or other third parties, other than advisors or consultants engaged directly by the ACCC, without first providing you with notice of its intention to do so, such as where it is compelled to do so by law. Please note that any information provided which you believe to be of a confidential nature should be clearly marked or identified as confidential.

We would be grateful for your response as soon as possible and in any event no later than **9 June 2009**.

Responses may be mailed to Ms Sheridan Burnett at the above address, faxed to (02) 6243 1212 or emailed (preferably in PDF format) to [mergers@acc.gov.au](mailto:mergers@acc.gov.au) with the title:  
*Submission re: proposed merger of Merck and Co. Inc by Schering-Plough Corporation.*

If you have any queries in relation to this letter or would prefer to discuss your response over the telephone, please contact Ms Burnett on (02) 6243 1296 or Ms Susannah Bolton on (02) 6243 1055.

Yours sincerely



Danielle Staltari  
Director  
Merger Investigations Branch

## Attachment A – Human Health Products

### General questions

1. Please describe your business or your area of speciality, including any relationship you have with Merck or Schering-Plough (the **merger parties**).
2. Who do you consider to be each of Merck's and Schering-Plough's closest competitors in the supply of:

- Allergic rhinitis treatments
- Systemic anti-fungal treatments
- Lipid management products
- Hypertension treatments
- Arthritis treatments
- HIV/AIDS treatments
- Asthma treatments
- Sarcoma treatments.

Please explain the reasons for your view (for example, with reference to companies which supply treatments which have similar action or effect, which are especially innovative in a particular class of therapeutic goods or which offer customers additional benefits/services).

3. Do you specialise in any of the therapeutic areas listed in question 2? If yes, please indicate which therapeutic areas and whether you would be willing to discuss your area of speciality in more detail with staff of the ACCC?
4. Do you consider that Schering-Plough or Merck is a vigorous competitor in any market? For instance, is Schering-Plough or Merck known as an innovator in a particular therapeutic area?
5. To what extent do you consider Merck and Schering-Plough compete on the basis of:
  - a. Price of products and services (e.g do the parties offer discounts on products and/or provide support services to patients, hospitals or medical practitioners)
  - b. Product quality and range
  - c. Research and innovation
  - d. Other non-price factors such as service, marketing and training.
6. To what extent do you consider the Government through the Pharmaceutical Benefits Scheme (**PBS**) is able to exercise countervailing power and bargaining power when agreeing on price and terms of sale with pharmaceutical manufacturers? How will countervailing power be affected by the proposed merger?
7. To what extent do you consider the PBS or other legislation constrains the merger parties' ability or incentive to compete on price?
8. To what extent do you consider customers (e.g. hospitals, pharmacies, wholesalers of pharmaceutical products, State Area Health Networks) are able to exercise

countervailing power? How will countervailing power be affected by the proposed merger?

9. Post merger, to what extent do you consider the merged firm would be able to increase the price of pharmaceutical products (this includes both over-the-counter (**OTC**) and prescription medicines)? Which pharmaceutical products do you consider the merged firm could increase the price of? What constraints would exist to prevent this occurring?
10. What effect do you think the proposed merger will have on the research and development activities for pharmaceutical products of the merged firm? For example, will the proposed merger be likely to increase, decrease or have no effect on the level of research and development?
11. What effect do you think the proposed merger will have on support services provided to users (e.g. patients, medical practitioners, hospitals or pharmacies) for pharmaceutical products supplied by the merged firm? For example, will the proposed merger be likely to increase, decrease or have no effect on the type and/or level of support services offered?
12. Do you consider the proposed merger is likely to result in a substantial lessening of competition? Why/why not?
13. Please provide any other information that you believe the ACCC should consider as part of its assessment of the proposed merger.

#### **Questions for pharmaceutical manufacturers**

14. Please describe your business including the products that you manufacture and the key therapeutic areas in which you are involved in research and development.
15. What would be required for a new pharmaceutical manufacturer to produce pharmaceutical products (including both OTC and prescription medicines)? In particular:
  - a. What steps must a new entrant take to set up business?
  - b. What regulatory requirements would need to be satisfied?
  - c. How long would it take to obtain the necessary regulatory approvals?
  - d. What costs would be involved in establishing the pharmaceutical manufacturing business and which of these costs are 'sunk costs'?
  - e. Are there any other barriers that would prevent or deter entry (e.g intellectual property on products, existing supply arrangements etc)?

How do these requirements differ for a new pharmaceutical manufacturer looking to produce pharmaceutical products which are off-patent?

16. Could you expand your existing pharmaceutical product range, in particular into those therapeutic areas listed in question 2? Why/why not? What would be required for you to expand your product range (e.g. how would you expand your product range, what type of costs would be involved)?

17. Do you have licences from other companies to manufacture pharmaceutical products? In particular, please outline:
  - a. Which company you obtained the licence from and for which products?
  - b. The terms of the licence arrangement?
  - c. Whether the licence arrangement is exclusive?
  - d. How and when the licence arrangements were negotiated?
18. Do you have any contract manufacturing arrangements? If yes, please explain for which products and with whom the arrangements are with.
19. What promotional activities, information, seminars, patient support, or other services do pharmaceutical manufacturers provide in addition to their products? Please explain the benefit of any additional services provided and why these services are provided.

#### **Questions for wholesalers/distributors**

20. Please provide an overview of your wholesale/distribution business in Australia. In particular:
  - a. From which manufacturers do you obtain pharmaceutical products?
  - b. What pharmaceutical products do you supply?
  - c. To whom do you distribute pharmaceutical products?
21. Do you receive any discounts on pharmaceutical products supplied by the merger parties? If yes, please describe the type of discount, in what circumstances the discount is provided, to which product(s) the discount applies and why the discount is provided.
22. Does Merck or Schering-Plough provide any support services to wholesalers or distributors? If yes, please describe the type of services provided.
23. Do you currently manufacture any pharmaceutical products in-house? Have you sponsored a manufacturer to produce a generic pharmaceutical product? Why/why not?
24. Are you aware of any wholesalers/distributors who have entered into pharmaceutical product manufacturing in the past 5 years, either directly or by sponsoring a new entrant?
25. Post merger, to what extent do you consider the merged firm would be able to increase the price of pharmaceutical products (including both OTC and prescription medicines) or reduce the level of service provided to wholesalers/distributors? What products do you consider the merged firm could increase the price on? What factors exist to prevent this occurring?
26. Post merger, if the merged firm was able to increase the price of its pharmaceutical products or decrease the level of service provided to you as a customer, would you be able to switch to another supplier? Why/why not? What would be involved in switching suppliers (e.g. what costs would be involved, how long would it take to switch suppliers)?