APMA Australian Pharmaceutical Manufacturers Association ABN 023 580 663

1 June 2001

Mrs Helen Owens
Presiding Commissioner
Cost Recovery Inquiry
Productivity Commission
Locked Bag 2
Collins St East Post Office
MELBOURNE VIC 8003

Dear Mrs Owens,

I am providing this second submission to the Productivity Commission Cost Recovery Inquiry on behalf of the Australian Pharmaceutical Manufacturers Association Inc (APMA). APMA is pleased to have the opportunity to appear before the Commission on Thursday 7 June 2001. At the public hearing we would like to raise the following issues in relation to the Draft report released on 12 April 2001.

APMA is in general agreement with the recommendations proposed in the Draft Report. In particular, we strongly endorse draft recommendation 6.2, that cost recovery arrangements should apply to specific activities, not to the agency that provides them, and draft recommendation 6.4, that cost recovery arrangements should not include the cost of activities undertaken by Government, such as policy development, ministerial or parliamentary services and international obligations.

APMA strongly agrees that the proposed Guidelines for Cost Recovery (Chapter 9) should apply to both existing arrangements for cost recovery as well as to any proposed future cost recovery arrangements. However, we are concerned that the Draft Report does not recommend sufficiently strongly that the Commonwealth Government should adopt a formal cost recovery policy for regulatory and information agencies and that existing cost recovery arrangements should be reviewed and revised as appropriate for conformity with the new policy (draft recommendation 4.1 refers).

Although it is stated in Chapters 9 and 10 that existing cost recovery arrangements should be reviewed using the Guidelines for Cost Recovery, there is no specific recommendation to the Government that this should occur. We suggest that a specific recommendation should be included in the final report.

We endorse the clear exposition in Chapter 4 of the Draft Report that annual charges imposed under the *Therapeutic Goods (Charges) Act* are effectively a form of taxation. Further, we agree with the suggestion in Chapter 9 (on page 221 of the Draft Report) that it is desirable to implement cost recovery arrangements using fees related to specific activities rather than using levies which are not closely linked to the costs of providing services and are less transparent.

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Currently the Therapeutic Goods Administration (TGA) obtains approximately 12% of its revenue from annual charges levied under the *Therapeutic Goods (Charges) Act*. Each year when the therapeutic goods industry Associations participate in discussions with the TGA about proposed increases in fees and charges, there is often consideration of increasing the annual charges to a greater extent in order to derive a larger proportion of overall TGA revenue from annual charges rather than from service-related fees which are subject to greater variability. It has been argued that such arrangements would provide more certainty in TGA's annual revenue, as the number of products attracting an annual charge is relatively consistent compared with fluctuations in numbers of applications. However, such an approach would seem to diminish the degree of transparency of cost recovery arrangements and may allow less pressure to be exerted on the TGA to minimise its costs and introduce efficiency gains.

In relation to whether fees or levies should be imposed under cost recovery arrangements, we suggest that Figure 9.3, Pre-market activities may need further review. If it is accepted that cost recovery arrangements comprise a mix of fee for service and levies, the decision tree in Figure 9.3 seems to suggest that a levy is not a form of cost recovery as it is portrayed as an alternative to cost recovery. We suggest that this should be clarified.

Thank you for the opportunity to comment on the Draft Report. We will be pleased to expand further on these matters at the public hearing on 7 June 2001.

Yours sincerely,

Deborah Monk
Manager, Scientific and Technical Affairs