

June 28, 2004

Ms. Kristie Mikus
Department of Commerce
14th and Constitution Avenue
Room 4039
Washington, D.C. 20230
drugpricing@ita.doc.gov

Dear Ms. Mikus:

I am pleased to submit the following comment in response to the *Federal Register* notice of June 1, 2004, 69 FR 30882, concerning the study of drug pricing practices in member countries of the Organization for Economic Cooperation and Development (OECD). The study was called for in section 1123 of the Medicare Prescription Drug Improvement and Modernization Act of 2003.

Novartis is a leading global health care company. Novartis' US operations are headquartered in New York. We have a substantial research presence in the US, with a recent move of R&D operations to Cambridge, Massachusetts. Employing over 78,000 staff globally, with approximately 20,000 in the US, our businesses include research-based pharmaceuticals, generic pharmaceuticals, consumer health care products, medical and infant nutrition products, animal health products, and vision care.

In general, three observations about the effects of drug pricing practices in OECD countries can be made regarding the quality of health care that is available in those countries, as well as the effect on the overall capacity for innovation in these markets:

- 1) Drug pricing policies which do not take into account the high cost of research and development of innovative pharmaceutical products in the relevant country will inevitably lead to a loss (or at least considerable delay) in making innovative drugs available in that country. This leads to a deterioration in healthcare and directly affects patient choice.
- 2) Faced with the inability to recoup research and development costs in a given market, companies will divert their R&D activities to those locations where they can be reasonably confident of earning back the considerable costs associated with innovation. Governments that impose unrealistically low prices on research-based pharmaceutical products encounter the unintended consequence of forcing R&D activities to move elsewhere.
- 3) Under the current approach to drug pricing outside of the United States, OECD governments are able to "free ride" – they have been able to impose artificially low prices for drugs at home, while assuming that the US market will continue to underwrite the development of new drugs. This lack of burden sharing is unsustainable.

To reflect views specific to Novartis with respect to questions posed in the *Federal Register* notice, I would like to provide the following comments:

Question

If price controls and other government cost control mechanisms were eliminated in OECD countries, how and to what degree would pharmaceutical prices and expenditures change in those countries and in the United States? What effects would these changes have on the sales and profits of pharmaceutical manufacturers?

Response

This would result in a larger price spread between innovative and generic drugs. The imposition of price controls has the perverse effect of disadvantaging the introduction of new drugs, making it impossible for companies to recoup research and development costs. A return to market-based pricing for drugs in these markets would make a fuller range of innovative products more readily available to consumers. Higher prices would give them access to the latest scientific inventions.

Price controls also reduce market-based competition among products which are poorly differentiated. Abolition of price controls therefore leads to a faster erosion of the price for such products. This is particularly the case after the loss of patent protection.

Question

What factors influence, and how do companies determine research and development expenditures? How would higher prices and revenues from sales in OECD countries affect R&D?

Response

Regional allocation of R&D expenditures correlates closely with the commercial potential of a new drug in the respective region or country. Where it is anticipated that a new drug has the potential to generate a high level of revenues, companies will work directly with local physicians and patient groups to promote knowledge about the effectiveness of the new product in the market.

Question

What is the relationship between increased R&D by pharmaceutical manufacturers and the introduction of new drugs?

Response

Increased R&D leads to more compounds being tested and developed, as well as the ability to run more clinical trials within a shorter period of time for such compounds. Therefore, the increased R&D activity leads to the availability of more and better differentiated products in the market. This provides significant benefits to patients and society.

Question

Could OECD countries reduce costs by increasing the use of generic drugs? What steps would the governments need to take to facilitate the use of generic drugs?

Response

Clearly OECD countries could reduce costs by fostering real market-based generic competition. Recent experience in the United States demonstrates that competition leads to rapid substitution of branded prescriptions by generic products.

Question

Are there means by which OECD countries could improve incentives for developing innovative medicines without significantly increasing spending on drugs?

Response

The issue is not whether spending on drugs is increased, but (1) whether patients benefit by longer duration and better quality of life; and (2) whether appropriate use of innovative medicines leads to reduction of expensive secondary and tertiary healthcare services (hospitals, institutions, nursing homes) that would otherwise be needed in the absence of the innovative products. One must apply a broader measure of the costs and benefits of the more widely available innovative products.

We greatly appreciate the opportunity to provide these comments, and appreciate the effort by the Department of Commerce to undertake this study and to gather relevant information from interested parties. Novartis is pleased to take part in this important effort, and we look forward

to working with Commerce and other US Government agencies as you continue the work on this analysis.

Sincerely,

Tracy Haller