

Novartis' comments on the European Commission's Preliminary Report on the Pharmaceutical Sector Inquiry

Novartis would like to submit the following comments on the Commission's preliminary report on the Pharma Sector Inquiry. Please note that in this submission we focus on areas where we see positive engagement of the Commission with regards to policy change, and the fact that we do not comment on other items of the report does not mean that we endorse its findings or its conclusions.

- a) Novartis regrets the Commission's reluctance to analyze the pricing and reimbursement policies of the member states;

Novartis takes the view that national pricing and reimbursement practices around Europe are the biggest single obstacle to generic competition. The preliminary report shows clearly that market entry differs significantly from one country to another. Countries with free pricing for generic products tend to have much quicker market entry than countries where prices have to be approved by authorities or where there are mandatory price decreases or other regulatory interventions.

- b) Novartis also refutes the Commission allegations that anti-competitive practices have led to delays in pharmaceutical innovation;

There are clear commercial signals that payers will not reward medicines that although efficacious and safe, provide what is deemed to be only small additional benefits to existing therapies. In other words, there are no incentives to continue the development of what payers dismiss as 'me too' medicines. This alone will probably explain the small decrease in new chemical entities that various commentators have noticed.

Furthermore and perhaps most importantly, there is indeed a shift in pharmaceutical innovation. However, the reasons for this have nothing to do with anti-competitive practices. Discoveries in pharmaceutical research have led to a focus on increasingly more complex therapeutic areas, and as a result, targets become more difficult. Most researchers' objective nowadays is to understand the pathway of diseases and the roots of the problem as opposed to treating only the symptoms of a disease. This leads to more effective medicines, but takes longer to develop, and often initially addresses a much smaller number of patients. There is thus a need for continuous development which often involves subsequent identification of categories of patients that could benefit from the same treatment.

This takes time but also significant investment. Most importantly, this continuous development is mistakenly seen by payers as mere 'incremental innovation' and there is a reluctance to reward it. If anything Novartis believes that there may be a need to revisit the possible regulatory rewards to companies for incremental innovation that improves the therapeutic scope and safety profile of existing treatments.

c) Novartis believes that another high priority for the European Commission should be the creation of a true single market for generic medicines that would allow generic manufacturers to develop economies of scale.

A high quality European patent as well as a single European Patent judiciary system would be important elements to overcome the present fragmentation of the markets. Novartis agrees with the Commission about the possible benefits associated with the introduction of a Community patent. Novartis welcomes in particular the idea of a unified European Patent judiciary system provided that its organizational structure and procedures would meet the highest standards of patent litigation. Improvements in the cost and efficiency of reaching timely decisions on patent disputes must however not override considerations as to quality. Quality of laws, procedures and the judiciary are key to quality of decisions which is one of the crucial factors to ensure a competitive, sustainable business planning for originator and generic companies that will finally lead to achieve and maintain high-level access of European patients to more innovative and generic medicines.

Furthermore, one should not ignore a number of additional regulatory barriers that also need to be addressed in order to create a true single market for generic companies. For example, the mutual recognition procedure does not support differentiation of dossiers for the same product in light of different patent situation across Member States. This means that generic manufacturers can rarely benefit from a single European market.

Novartis is happy to work with the European Commission to provide further clarifications on the above issues.