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Innovation for Growth and Competitiveness

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Ladies and gentlemen,

I am pleased to be here in Paris, on this panel to discuss the topic of innovation for growth and competitiveness.

My company, Merck Sharpe and Dohme has had a longstanding relationship with the OECD and we are grateful for your organization's commitment to engaging the private sector as a valued partner in many of your activities, and especially on matters of health care policy.

Life-science innovation offers tremendous possibilities when it comes to improvement in health and wealth. The OECD governments are making a concerted effort to invest in this sector and to foster its growth several ways. They are working to attract and retain highly-educated researchers, support infrastructure conducive to scientific development such as clusters of innovation, cultivate closer academic and industry collaboration, provide R&D incentives, and assure more reliable intellectual property protection and enforcement.

Yet as a high-technology pharmaceutical company striving to bring steady improvement in human health, we face the paradox of continually increasing market barriers and decreasing incentives to develop and disseminate new products.

In an effort to restrain costs, governments are instituting restrictive mechanisms, creating an environment that not only hinders innovation but may also negatively affect health itself. This situation contrasts significantly with that facing many of the other high-technology industries, which also are competing to offer innovative products to their customers.

Although solutions are difficult, it is possible to improve the balance between incentives for health innovation and other social goals such as equitable access to innovative products at costs that are affordable. The key to making this happen is through enabling innovation and competition, while at the same time ensuring value for money.

In the recent and influential Aho Report (named after its Chair, the former

Prime Minister of Finland) independent experts called for a Pact for Research and Innovation in Europe. Its core recommendation, which is crucial for our industry, is the need to provide **an innovation-friendly market**.

The innovation-friendly market for business requires progressive regulation, attainable standards, effective patent protection, market-led competition, strong intellectual property protection, and an environment fostering a culture of innovation. Unfortunately the pharmaceutical industry in Europe has been forced to face conditions that contradict the desired goal of increased innovation, and as a consequence, impede the delivery of new and improved health care products.

When taken in isolation, the regulatory environment that our industry enjoys in Europe is harmonized in its structure such that it probably serves as a model for other industries. The European Medicines Agency (EMA) provides scientific evaluation of applications for European marketing authorization for an increasing number of products that go through its centralized procedure. This process requires only a single submission for the entire EU and has been accomplished through years of harmonization and standard setting such as "good clinical practice", "good manufacturing practice", "good laboratory practice" and others. EMA sets the stage for efficient and transparent procedures to allow rapid access by users. EMA approves drugs as quickly and sometimes more quickly than FDA.

At the same time however, the European market is fragmented. So, while the speed of approvals – vital for innovative companies relying on patent protection to recoup their R&D costs, has been greatly improved, the dynamics of market development in Europe lags significantly behind the US, slowing access to new products for European citizens. Government and public payers in most countries differ greatly in their valuations of products, and take a long time agreeing on their prices and reimbursement levels. Consequently, citizens of one country still wait several years for access to the new products already available in other European countries. Slower and unequal access to new drugs in Europe not only deprives patients of new available treatments but it also unnecessarily raises the costs of diffusion of new products for companies.

With the globalization of science we are also witnessing the explosion of information and improved understanding of its implications on health. As a consequence, the European patient is increasingly aware of the existence of new medicines. Yet, patients and doctors in Europe are increasingly likely to be deprived of healthcare choices; concerns about the rising costs of pharmaceuticals are driving governments to restrict access to innovation. Further, these concerns push governments to deny rather than adopt documented improvements in standards of care--standards based on the newest scientific insights for treating the disease.

The measures applied by governments often work by limiting market competitiveness. Governments increasingly apply simplified terminology—type-casting—on innovative products, classifying them as "breakthrough", "incremental" or "imitative", and then regulate their pricing and reimbursement accordingly. This approach completely overlooks a complex relationship: that between advances in our understanding of diseases, diagnostics and treatments, and our ability to develop, test and commercialize products based on this understanding.

One anti-competitive device employed by government agencies in many countries is so-called "therapeutic reference pricing", where the value of an innovative patented product is referenced against the price of the established treatments on the market, including off-patent products which are deemed therapeutically equivalent.

Such linking of the branded and generic prices is not only anti-competitive but also fundamentally anti-innovative, and ultimately undermines the value of patents. In a market environment, price differentials between patented products and generics would be relatively large because they reflect the value of innovative effort and a different cost structure of the research-based industry. Academic research has documented that many of the significant developments in treatment of chronic diseases – hypertension, depression, diabetes, to name a few - might not have taken place if anti-innovative measures such as therapeutic reference pricing had operated on a global basis.

In light of this, it is troubling that governments are increasingly using this mechanism. Indeed, even the UK, whose stable, free pricing system has provided a solid platform for investment in the development of new medicines, is considering therapeutic reference pricing as one option. We believe that to move away from the current principles would be a mistake, and ultimately not in the best interests of patients.

This leads us to pose the question, and that is...

How can we go forward? How can we achieve the balance between innovation and social goals, at costs that are affordable to governments?

Facilitating access to innovation in healthcare can only be improved by fostering greater competitiveness. Governments should discontinue practices such as reference pricing for new patented products and allow market forces to achieve efficiencies, as they inevitably will in the presence of market-based competition.

We at Merck want to ensure that we are pricing our medicines and vaccines appropriately to the value that they provide. And, we hope that the attention to value will provide us with a competitive advantage.

At Merck we are aligned around the idea of providing and demonstrating value to customers including governments that pay for medicines. We want to make sure that we are developing medicines and vaccines that will provide value for money. This includes not only developing breakthrough products but doing the studies that demonstrate the clinical and economic value of these products.

We must also recognize that value for money can be achieved without restrictions of choice. Pricing and reimbursement should retain the incentives for doctors and patients to choose products based on value and risk/benefit ratio in individual cases.

Merck remains a willing partner in working with governments, patients, doctors and insurers. We believe that solutions can only be obtained through a dialogue around shared goals. Together with the industry we are participating in a **High Level Pharmaceutical Forum**, a multi-stakeholder process established by the European Commission, charged with the responsibility to balance the issues of innovation, access and affordability.

Work within the OECD could be extremely helpful in two ways. First, an initiative to develop a set of specific conditions necessary to enable healthcare innovation would be tremendously worthwhile. In particular, the various government ministries represented at the OECD could establish jointly the criteria for assessing the impact of different economic regulatory measures on innovation in healthcare.

Second, the OECD could provide better tools to measure the economic and societal value of medical technologies, and the value of health care spending in treatment of diseases over time. This means capturing both the dramatic decreases in cost of novel medications when they go off-patent and the improved outcomes of newly patented innovative medicines. Without better insight into this basic issue at a macroeconomic level, we will continue this **paradox of promoting investment in innovation, while at the same time questioning its value when the time comes to disseminate it.**