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ENABLING INNOVATION IN LIFE SCIENCES

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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.

However, a high-technology pharmaceutical company, striving to bring steady improvement in human health, faces a 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, also competing to offer innovative products to consumers.

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.

The regulatory environment that our industry enjoys in Europe has a harmonized structure such that it serves as a model for other industries. The European Medicines Agency (EMA) scientifically evaluates an increasing number of product applications for European marketing authorization via a centralized procedure. This process requires only a single submission for the entire EU and has been accomplished through years of harmonization and standard setting.

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.

Concurrently however, the European market is fragmented. While the speed of approvals has been greatly improved, the dynamics of market development in Europe significantly lags the US, slowing access to new products for European citizens. In most countries government and public payers 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 diffusion costs 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. Thus the European patient is increasingly aware of the existence/availability of new medicines. However 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.

Government measures often work by limiting market competitiveness. They 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 overlooks a complex relationship between advances in understanding of diseases and treatments, and the development and commercialization of products based on this.

One anti-competitive device employed by government agencies in many countries is so-called "therapeutic price referencing", 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.