

Press release

Pharmaceutical Sector Inquiry - a Missed Opportunity

Preliminary report fails to address real issues impeding patient access to innovative medicines and the urgent need for a more efficient generic market in Europe

Brussels, 28 November 2008 – The Commission acknowledges that the pharmaceutical industry is vital to the health of Europe's citizens and that patents are key to providing reward for innovation and incentives for future research, notes EFPIA, the voice of the research-based pharmaceutical industry in Europe, in commenting on today's "Preliminary Report on the Pharmaceutical Sector Inquiry". EFPIA calls for a more competitive generic market that would create significant savings that can be reinvested to give more patients faster access to innovative medicines.

"The preliminary report does not adequately recognize the complex and highly regulated nature of the pharmaceutical market in Europe and misses the opportunity to address the real issues impeding innovation and the development of and access to innovative medicines" said Arthur J. Higgins, CEO of Bayer HealthCare and President of EFPIA. "The report also overstates the level as well as the reasons for delays in generic market access. In line with EFPIA's own findings, DG Competition's analysis has confirmed that where there is a strong commercial incentive, generics enter the market rapidly within 4 months or less. This compares very favourably with the delay in access by patients to innovative products which can be up to 14 months in some EU markets."

The Director General of EFPIA, Brian Ager, added, "The Commission's report does not substantiate in any respect their statement made at the opening of the inquiry that the industry is impeding innovation. Over the last few years pharmaceutical research companies have continued to make breakthrough advances in complex therapeutic areas such as cancer, rheumatoid arthritis and HIV/AIDS for the benefit of patients."

EFPIA was also disappointed that DG Competition has used selective quotations to seek to mischaracterize the industry as anticompetitive. Those quotes simply show how innovators have rightly sought to protect their inventions and illustrate the highly competitive nature of innovation in this sector, which is entirely to the benefit of society. They are not evidence of competition law infringements as the report itself recognizes – it states expressly it reaches no such conclusion.

In looking at the access delays of generics, the report does not address inefficiencies in the generic market nor why European citizens pay less for innovative medicines but more for generic medicines than US citizens. A more market-oriented mechanism is necessary to ensure an efficient generic market that generates appropriate savings for healthcare systems. The report's headline is that swifter generic entry would have achieved savings of EUR 3bn over 8 years across 17 countries, that's EUR 375m a year. The same report fails to emphasise, however, that a single member state, the Netherlands, achieved greater savings – up to EUR 400m - in one year, on only 33 medicines, simply by promoting active price competition between generics.

The report acknowledges that patents are key to pharmaceutical innovation and should be protected. It then contradicts itself by questioning the right of the industry to use perfectly lawful practices – such as patent portfolios, patent litigation and the release of improved medicines. These are essential for innovators to protect their huge investments in R&D. Indeed the interim report acknowledges that the industry spends 17% of its turnover on Research and Development which is

more than any other industry sector in Europe. Furthermore, the report does not establish that such activities deter generic entry because the facts on generic entry tell a different story.

“We also acknowledge the conclusion that a Community patent could reduce costs and bring more legal certainty. EFPIA is already actively engaged with the Commission on the development of a cost-effective litigation system that provides legal certainty and above all gives high quality decisions,” added Mr Ager.

EFPIA is ready to work closely with the Commission as it has with the High Level Pharmaceutical Forum and the Innovative Medicines Initiative to remove impediments to innovation and improve access to new medicines for the interest of the health and wealth of European citizens.

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About EFPIA

EFPIA represents the pharmaceutical industry operating in Europe. Through its direct membership of 32 national associations and 43 leading pharmaceutical companies, EFPIA is the voice on the EU scene of 2,200 companies committed to researching, developing and bringing to patients new medicines that will improve health and the quality of life around the world.

The pharmaceutical industry accounts for no less than 19,3% of global business R&D expenditure. It is the sector with the highest ratio of R&D investment to net sales (15,9%). However, between 1990 and 2007, R&D investment in United States grew 5.2 times whilst in Europe it only grew 3.3 times, and there is rapid growth in the research environment in emerging economies such as China and India.

Today around 645,000 people work in this sector and it is estimated that three to four times more employment is generated indirectly both upstream and downstream. A significant proportion of people employed are highly skilled and 107,000 work in research and development. The European research-based pharmaceutical industry generates a substantial trade surplus, which was estimated at about €49,000 million for 2007. It has contributed significantly to reducing the European Union's trade deficit in high-tech products – today almost a quarter of the EU's high-tech exports are pharmaceutical products.