



Press statement Arthur J. Higgins, EFPIA President and CEO of Bayer HealthCare, on the Annual Meetings 2009 of the research-based pharmaceutical industry in Europe (EFPIA) in Seville, 13-15 May:

“Fostering health in an economic crisis environment -Investing in healthcare and a strong pharmaceutical industry is a prescription for economic recovery”

Ladies and Gentlemen,

The world economy is witnessing the most severe downturn for decades. With economies contracting, unemployment rising and national debts growing, there is a real risk that resources devoted to both health and innovation will be negatively affected. The consequences for the health and wealth of European citizens from such measures will be felt long after the current economic recession is over. The industry is likely to suffer from cost-containment measures imposed in response to budgetary constraints, as well as from increased difficulties to access liquidity from capital markets.

This is the case for the biotech sector. Indeed, a recent report by a French research group has suggested that funding shortfalls are putting one in five of Europe's small biopharmaceutical companies at risk of bankruptcy by year-end. This could mean the possibility of 20,000 highly-skilled jobs being lost, with a permanent damage to Europe's research capital.

Ladies and Gentlemen, this recession could prove to be a tipping point for our industry. And for those policy makers who think it is ok to squeeze the pharmaceutical industry, they should realise that by punishing this industry, they are in fact compromising the ability to develop life-saving drugs and undermining a strategic sector that is a cornerstone of Europe's knowledge-based economy. It is ironic that while sectors like banking and automotives are receiving substantial

financial support from our governments to remain solvent – some would say being rewarded for their underperformance and bad management - the pharmaceutical sector, which is a high performer and has not sought for any support, is still seen as a cost-driver rather than a value-driver. And this is where logic fails.

Our industry is a major creator of wealth and innovation, accounting for 3.5% of the total EU manufacturing added value and for 19% of the global business R&D. With Europe a net exporter of medicines, the pharmaceutical industry contributes significantly to the EU trade balance, providing a surplus of around 52 billion Euro in 2008.

And the contribution of our industry goes far beyond simple finance. We employ directly 635,000 highly-skilled people in Europe, of these more than 117,000 are in R&D, and - indirectly - over 2.5 million. Furthermore, we invest 17% of our turnover on R&D, which is far more than any other sector. Thanks to this investment in R&D, we develop life-saving drugs that respond to unmet medical needs. An excellent example of how society depends on our industry is being seen in the current threat of the swine pandemic, which could not be addressed without our antivirals and flu vaccines.

The pharmaceutical sector is thus a key asset to Europe's society, its science and its economy. And this important contribution needs to be recognised and nurtured by policy makers.

Ladies and Gentlemen, the challenges we are facing are unprecedented. But even in these troubled times it is important not to lose sight of the fact that health and the economy are closely interlinked and that investing in health is an investment in our future. A healthy population underpins a thriving economy, providing a strong, dynamic workforce who places fewer demands on healthcare systems. Investing in health also creates high-quality jobs and drive demand for goods and services. Against this background, the current economic recession should not be used as yet another justification for cuts in health and pharmaceutical expenditure, but rather as a real opportunity to make our healthcare systems fit for the 21st century. It is time for new, bold and creative thinking, thinking that recognizes healthcare not only as a societal need but also as a source of competitive advantage worthwhile of investment.

Properly functioning healthcare systems and a strong pharmaceutical industry are indeed essential remedies for economic recovery. This is something the current American administration seems to have understood, as it is investing strongly in healthcare as part of its route out of recession. For its part, Europe needs to be careful not to be caught in the old way of thinking, that is looking for short-term gain at the expenses of long term pain. Instead, it should focus on laying the foundation for sustainable growth.

But what needs to be done to help create modern and sustainable healthcare? How do we make Europe healthier and more competitive? We need to focus our efforts on five areas. Let me briefly go through each of them.

Firstly, we need greater efficiency in the way healthcare is financed and delivered. With limited resources available, EU governments should look at how to diversify their sources of funding. This should include a greater role for private health insurance and appropriate measures for patients to accept more responsibilities for their healthcare costs, while at the same time ensuring affordability and equal access to healthcare for everyone.

In addition, the savings generated from a more efficient use of off-patent medicines and generics need to be reinvested in new and innovative drugs. This will provide headroom for innovation. Governments should consider pharmaceutical expenditure in the overall context of healthcare. This means breaking out of a silo-budget approach and recognizing the benefits that medicines bring to healthcare systems. Very few governments seem to realise that medicines are some of the most cost-effective healthcare technologies available, reducing the direct costs of patient care.

Moreover, to increase cost-effectiveness the healthcare provision needs to be closer to the patient. In particular, policies that allow for more rapid Rx-to-OTC switches and promoting an appropriate use of OTC products should be encouraged.

Secondly, we need an improved regulatory and policy environment

The policy and regulatory environment needs to be improved so to provide better support to the development and early adoption of new drugs. There also need to be a more structured and timely dialogue between industry and public authorities. In particular, governments and industry should consider health priorities and targets as part of a long-term strategic agenda, not just for opportunistic, short-term cost-containment measures. Regulatory authorities should encourage an appropriate risk-benefit balance and provide the industry with clear and transparent guidance for drug approvals. Pricing and reimbursement processes should be expedient and transparent and allow for early and equitable patient access to medicines. They should also offer appropriate reward for innovation, including stepwise advances in therapy. This means that Health Technology Assessments should be used as tools to identify innovation and achieve better value for money, not as a means to restrict or delay access.

Thirdly, there should be a holistic approach to disease prevention and control

We have long been too short-sighted in funding prevention programmes, and we must avoid using the current economic crisis as another convenient excuse for that short-sightedness to continue. What is needed is a "whole-of-society" approach to disease-prevention and control; this will improve healthcare outcomes and in turn avoid significant spending over time. Consider the benefits of reducing morbidity from so-called "lifestyle" diseases. Conditions like cardiovascular and chronic respiratory diseases, diabetes and obesity are often caused by known and avoidable risk factors, such as an unhealthy diet, a lack of physical activity and smoking. Clearly, effective prevention in these areas would significantly reduce the burden these diseases have on healthcare systems.

Fourthly, we need to increase the innovation potential of our industry

New health challenges and an ageing society increase the likelihood of chronic diseases. This in turn demands a continuous effort in biopharmaceutical innovation.

Yet, despite a substantial increase in R&D investment in the past 10 years, the number of approvals of new chemical entities has at best remained constant. The productivity and ability innovate of our industry needs to be improved. This means more funding and incentives for R&D as well as more public/private partnerships.

The drug development process is far too complex for companies to efficiently address safety and efficacy predictions of new medicines alone. A new spirit of cooperation in the area of pre-competitive research would speed up and optimize R&D processes through rapid knowledge-sharing.

The Innovative Medicine Initiative, a joint venture between EFPIA and the EU, is an excellent example of successful multi-stakeholder partnership which is helping to reduce bottlenecks in drug discovery and boost R&D in Europe, and partners should continue to support it, especially in these times of crisis.

Finally, we need greater patient empowerment. Empowered patients take a more active role in managing their health. This leads to healthier behaviours and better compliance. Healthcare systems should be geared to offer more choice, more personalized care and effective patient involvement.

In other words, we should move from a paternalistic model, relying on the state and medical professions to set priorities and decide what is in the patient's best interest - to a model which is patient-centred, and where healthcare is designed and delivered to address patients' needs and preferences.

Patients will no longer accept being passive recipients of healthcare and advice. Instead, they want to become more knowledgeable consumers, with better access to quality information about their diseases and treatments and more control about decisions affecting their health.

Regrettably, to date I have not seen the political will to fully enable a proper access to health and drug information for patients in Europe.

Ladies and Gentlemen, Fostering health must be a shared commitment. Only a concerted multi-stakeholder approach can deliver the high quality healthcare we all need, and this even more in times of recession. Indeed, we all have a responsibility to avoid the current economic crisis from also becoming a social and health calamity.

In this context, I would like to highlight a positive examples of measures taken to tackle the current situation in a constructive and collaborative way. I am referring to the joint agreement by the Spanish Ministry of Health and Farmaindustria, the Spanish pharmaceutical association to “help the pharmaceutical sector emerge from the crisis better positioned”.

From 2009 until 2011, Farmaindustria has committed to maintain and improve employment levels; increase R&D investment by 15%, achieve drug exports of 22,5 € million and invest €180 million in public/private- projects promoting the rational usage of medicines and fostering clinical and translational research. In return, the government has promised a more stable and predictable regulatory environment and greater dialogue with the industry.

I would like to conclude with an appeal to policy makers:

That is, to recognise that healthcare is not a luxury to be squeezed in times of crisis but instead to see it as a primary need that cannot be allowed to fail, as it plays such a pivotal role in our society and economy.

Our governments need to be smart enough to realise that a strong healthcare and pharmaceutical sector is the right therapy for economic recovery. Therefore, they should not shy away from investing in healthcare and instead undertake the fundamental reforms our healthcare systems so desperately need. The pharmaceutical industry stands ready to work with policy makers and all other key stakeholders to deliver modern and sustainable healthcare which is fit for the 21st century, where unmet medical needs are addressed, innovation is rewarded and patients have rapid access to the fruits of that innovation and investment.

Thank you