

Presentation of the Preliminary Report of the Pharma Sector Inquiry
CHARLEMAGNE BUILDING / ROOM ALCIDE DE GASPERI
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INTRODUCTION STATEMENT

Ladies & Gentlemen,

On behalf of the European research-based pharmaceutical industry, I am pleased to be here today to discuss some of the key issues facing our sector as well as to dispel a number of myths or misunderstandings surrounding it.

Throughout the inquiry our member companies have worked extremely hard and in a very transparent manner to ensure the Commission has all the information they need.

We did this willingly because we hoped this inquiry would provide an opportunity to present facts about the challenges and functioning of our sector, and to avoid an emotionally charged debate dominated by the influence of special interest groups.

The key question I am asking today is: are we here to discuss how to enhance innovation so that patients can continue to access life-saving medicines or do we want to focus on further building the myths and mischaracterisations which may make good news headlines but will in the end only serve those who want to undermine this industry?

I was therefore 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. It is important to note the report itself states it reaches no conclusion as to any competition law infringement.

If we truly want to look after the health of European patients and enhance the competitiveness of Europe by supporting one of its most vital industry sectors, then I believe that we should stay focused on the facts rather than the myths.

In this spirit, let me now address some myths and share with you the facts:

Myth number one: the research-based pharmaceutical industry is stifling innovation

This first myth is what supposedly prompted the sector inquiry into our industry.

The facts are, as the Commission acknowledged, that our industry is vital to the health of European citizens and there is nothing in the report that substantiates the allegation that our industry is hindering innovation. This is not surprising, as our very business model is based on innovation; without it we would simply not exist.

Indeed, our commitment to innovation remains unmatched by any other industry. As the interim report acknowledges, we spend 17% of our turnover on R&D, which is far more than any other sector.

Myth number two: the pharmaceutical industry's innovativeness is declining

The reality is that our industry is no less innovative than 10 or 20 years ago. Pharmaceutical companies have continued to make breakthrough advances in complex therapeutic areas such as HIV, cancer and many other diseases.

The Commission concludes there is a decline in innovation based on new molecules launched. But this simplistic analysis is sensitive to time period - the approval of new active substances in the EU has actually increased between 2005 and 2007 from 28 to 40 according to the EMEA. We believe that measuring innovation on the basis of a simplistic count of new molecules does not take into account the many different facets of innovative activity and is not meaningful in an industry where product research and development cycles span over 10 to 15 years.

What is needed is a more holistic approach to measure and understand innovation, including the value of incremental innovation. An approach that goes beyond numeric outputs to reflect the *value* those outputs bring to society and the patient. Advances in biomedical sciences mean that a single molecule can act on targets which can be involved in a number of diseases, resulting in multiple therapeutic uses.

The industry's contribution to the understanding of the genetic code, proteomics, combinatorial chemistry, and bioinformatics are other equally important measures of innovation.

[CHALLENGES BEHIND INNOVATION]

However, what is clear and perhaps where the misunderstanding comes from is that we are indeed facing increased challenges in developing new medicines and that our R&D productivity has declined. The cost of

innovation has risen dramatically, with the average cost to develop a new product now exceeding €1 billion.

The reasons for this are complex, but are surely not to be found in any alleged anti-competitive practices vis-à-vis the generic industry.

The facts are that despite significant advances in science and technology, **attrition rates** and the risk inherent in pharmaceutical R&D are extraordinarily high. As we as an industry are pushing the boundaries of sciences and biology and searching for new disease targets, we face increased challenges in R&D.

Moreover, **regulatory hurdles** and a **shift by regulators towards risk avoidance** have increased the cost and complexity of clinical trials; while ever changing **pricing** and **reimbursement policies** undermine innovation and reduce commercial certainty.

In this context, we regret that the inquiry fails to address competition distortion caused by state regulatory, pricing and reimbursements regimes which are the critical factor in understanding how pharmaceutical markets work or, more importantly, do not work for the benefit of patients.

Myth number three: The research-based pharmaceutical industry is against an efficient generic sector

This may come as a surprise to you but the research based pharmaceutical industry is actually in favour of an efficient generic market. The reason why is quite simple and self-serving. We hope that more efficient price competition between generic companies will create significant savings that

can be reinvested to give more patients faster access to innovative medicines. We see this as “headroom for innovation.”

In this respect, we believe the Commission has largely overstated both the level as well as the reasons behind delays in generic market access.

[GENERIC ENTRY]

Concerning the level of generic market access, the Commission’s analysis has confirmed – again not surprisingly - that where economic incentives are highest, generics enter the market within 4 months or less after loss of exclusivity. Analysis done by EFPIA suggests that in most cases where the profit incentive for generics is high this happens within 3 months.

If we are genuinely interested in the health of European patients, we should be asking why it is the case that for life-saving, innovative medicines patients face regulatory delays of up to 14 months.

Ladies and Gentlemen, our conclusion is that when there is a commercial desire and motivation to do so generic market entry is almost instantaneous.

Myth number four: The research based pharmaceutical companies use a toolbox of inappropriate measures to delay generics entry

First we welcome the Commission’s acknowledgement that patents are key in the pharmaceutical sector and should be protected in order to encourage innovation.

Clearly patents are of no value if the right holder cannot enforce them. It is then contradictory that the report questions the right to a legitimate use of legal measures - such as patent filing, litigation, life cycle management and settlement agreements – which are available to us as to any other industry to protect patents from infringement.

Responding to the allegation of patent “ever-greening”, I would like to point out that you cannot extend one patent by obtaining a later patent. Patents are not granted lightly, but are subject to a highly rigorous process to test the level of novelty. Only genuine innovations get approval while later patents reflect incremental innovative steps, such as a new manufacturing process or new formulation.

As the report shows, generic entry is in fact getting faster over time which is clearly inconsistent with the claim that our industry has effective measures to impede generic entry.

Myth number five: generic entry delays represent a significant cost to European healthcare systems

Concerning the question of costs of generic delays to healthcare systems, we were disappointed to see that the report has not at all addressed the issue of competition between generic companies nor the inefficiencies of generic pricing within the Member States.

As a business man looking at the simple economics, if I wanted to make savings and reduce the burden on European consumers, my focus would not be on reducing the almost instantaneous entry of generic from 4 or 3 months to zero, but rather on ensuring more competitive generic prices.

The key question is why US citizens pay so much less for generics than Europeans.

The lack of analysis of generic competition is a crucial omission from the report. The headline of the report is that health budgets could have saved EUR 3bn over 8 years, across 17 countries, that's EUR 375m a year, if generics entered earlier. I calculated this as less than one Euro per European citizen. However, the same report fails to emphasise its own finding that a single member state, the Netherlands, achieved potentially greater savings – up to EUR 400m - in one year, on only 33 medicines, simply by promoting active price competition between generics. Ladies and gentlemen, this is what they should have focussed on.

Myth number six: our industry is more interested in marketing than R&D

Let me now touch on another myth which is implied indirectly in the Commission's report, namely that the industry is more interested in promoting our products rather than in researching new medicines.

Firstly, marketing is a normal part of doing business and in our sector is certainly costly, but it should be noted that we do not engage in marketing in the sense used in other industries. What the Commission refers to as "marketing" is the highly regulated process by which companies inform healthcare professionals about the advantages and disadvantages of a drug. This information is vital for informed choice and to ensure that patients receive the right medicines.

But the cost of marketing in no way detracts from our commitment to R&D. The Commission has identified in its own report that we spend 17% of sales

on research and development and approximately 23% on promotion. This ratio has no equal in any industry. Furthermore, in recent years, faced with profit challenges, the industry has been reducing expenditure on promotion to protect R&D budgets. This clearly reflects my opening remarks that the survival of this sector does depend on innovation, and not promotion.

Myth number seven: new medicines can be developed by academia or small and medium enterprises so it does not matter if the research-based pharmaceutical industry is weakened

People who promote such a myth are doing a great disservice to the health of European patients and are undermining the strength of the European economy. The reality is that academia does not create new medicines. As for small enterprises, there are very few examples where they have the ability to bring new medicines to the market.

While it's essential that we collaborate with academia and SMEs, the complexity and the prohibitive cost of developing new medicines can only be borne by the pharmaceutical industry.

[THE RIGHT FRAMEWORK CONDITIONS]

Ladies and Gentlemen, as I said earlier in my presentation we have a decision to take. We can either focus on the myths and misunderstanding which do nothing to improve the health or wealth of European citizens, or we can concentrate on the facts and then look at how we can continue to work together in a spirit of cooperation and trust with the goal to strengthen the innovativeness of our industry and in doing so improve the health and wealth of European citizens.

I believe that in the end, we all share the same goal, namely to ensure the continuous discovery and development of life-saving medicines and that these swiftly reach the patients who need them.

In this regard, let me remind you that it is only by putting in place the right framework conditions - such as strong intellectual property rights; a clear regulatory environment; fair and transparent pricing and reimbursement policies that reward innovation and ensure swift patient access - that our industry will be in the position to continue to innovate, for the benefit of millions of citizens in Europe and beyond.

[CONCLUDING REMARKS]

Ladies and Gentlemen,

I hope I have established beyond doubt that it is not in our interest to delay generics or restrict innovation and if there are deficiencies in the system, we are the first ones that want to address them. We are fully committed to cooperate and engage in an open dialogue with the Commission and relevant stakeholders on issues raised by this inquiry.

In these economically challenging times it is vital for Europe to focus on its high technology industries. The EU Commission has clearly identified the pharmaceutical sector as a priority sector. So by attacking and undermining our industry we are not only damaging patients but also the economy.

The fact that we can collaborate in a positive way is demonstrated by the Innovative Medicines Initiative, a joint ground-breaking initiative by the European Commission and the research-based pharmaceutical industry which research Commissioner Potocnik and myself launched only a few months ago in this very room. With IMI our industry committed 1 billion € to

enhance biomedical research in Europe so that better and safer medicines can be developed.

Today, we also call on public authorities to identify and implement the necessary steps to create an environment that sustains pharmaceutical innovation. In this context, the long-awaited pharmaceutical package is a good step in the right direction, and we ask for its rapid approval by the European Commission.

So on behalf of European patients of which I and everyone in this room is or ultimately will be – let's not spend our energies recycling old myths, but focus our considerable resources on positive initiatives like IMI and the pharmaceutical package. This is where we can truly serve the interests of European patients.

THANK YOU