Delivering Patient-Centred Innovation in Medicines

Stationers' Hall, London, 1 December 2005

Department of Health

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UK PRESIDENCY OF THE EU 2005

"This is our opportunity to influence the European environment for the innovative pharmaceutical sector. Creating the right conditions for investment and growth is so important, both for our economies and the health of our citizens."

Jane Kennedy MP, Minister of State for Quality and Patient Safety, Department of Health

Delivering Patient-Centred Innovation in Medicines

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An event of the UK Presidency of the European Union
Stationers' Hall, London, December 2005

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Summary and Key Priorities

1. The pharmaceutical industry has a crucial role to play in the achievement of two of the major objectives of the European Union – improved levels of healthcare for all citizens, and the Lisbon objective of increased EU economic competitiveness on the global stage. It therefore gave the UK great pleasure to host this high-level meeting during the UK Presidency of the EU.

2. It had been two years since the Health and Competitiveness Councils adopted the G10 medicines report, and as we all begin work on the European Commission's new pharmaceutical strategy it was important to remind ourselves of the aims of the G10 report, and to consider how the report's recommendations could be adopted in all member states.

3. The need for a strong pharmaceutical industry in Europe is accepted by all member states, and this was demonstrated by the discussion. We would like to express our thanks to all those who attended and contributed so openly to the round table discussion. We had 34 delegates at the event, including three patient groups, crucially bringing to the table the views of the people who actually take medicines; leaders from the pharmaceutical industry; and senior representatives from the European Medicines Agency and the European Commission. We are very grateful to our fellow ministers, both from the EU and candidate countries, and to senior officials from governments and companies, who took the time to share their views and to listen to those of others. We greatly appreciated the comments that were made and the frankness with which all were able to exchange views throughout the discussions.

4. It was not possible to do justice in a brief summary to all of the points made during the meeting, and the transcript of the round table discussion is reproduced later in this report; but we would in particular like to draw attention to the addresses given by Hans Hoogervorst, Netherlands Health Minister; Richard Barker, of the Association of the British Pharmaceutical Industry; Franz Humer of the European Federation of Pharmaceutical Industries and Associations; and Heinz Zourek from the European Commission. The transcript also records the contributions made by all the other delegates: member states, industry leaders, regulators and patient group representatives.

Why should the European Union want a competitive pharmaceutical industry?

5. As we all work towards the first meeting of the Pharmaceutical Forum it is important to remind ourselves why Europe needs a competitive pharmaceutical industry. The industry develops innovative medicines that preserve health, prolong lives, and bring a variety of

substantial economic benefits. As a major contributor to European business R&D, a vigorous, thriving pharmaceutical industry is essential for Europe's overall industrial competitiveness. But growth in pharmaceutical R&D investment in Europe has been falling behind the US for many years, and we must ensure this trend is reversed, and that we also rise to the challenge from emerging Asian competitors. If we fail, we will lose potential investment, highly skilled jobs, technological innovation, academic collaboration and management expertise.

6. But that is only a part of the picture: we will also lose the benefits to patients of being able to take part in clinical trials of new treatments, and the esteem and experience for our doctors in being involved in carrying out these trials. Member states invest for the future through our education systems. We develop high-quality graduates, and we should aim to get the benefit from this investment through ensuring that the conditions are right to attract the pharmaceutical industry, and other knowledge-based industries which can provide the quality of jobs that will keep these graduates in Europe, and to ensure that the bioscience discoveries made in European universities and institutes are developed into world-leading medicines here.

7. It was recognised that pharmaceutical investment varies across Europe. Some countries are host to R&D operations, some to manufacturing, either of branded medicines or generics. Each of these has an essential role in bringing new and affordable medicines to patients, but we should not forget that they all need good market conditions to be competitive, and that is the challenge for the European Commission, each member state, patients and industry to achieve.

How can European Union governments and industry work together to provide European patients with innovative and affordable medicines?

8. The challenge of how European Union governments and industry can work together to provide European patients with innovative and affordable medicines is not a simple one to resolve. But we are in a good position as the G10 report has already made a number of recommendations that could make a significant difference to the attractiveness of Europe for the pharmaceutical industry. Several of the G10's recommendations were in effect dealt with by the outcome of the 2001 Review negotiations. However, a number of important recommendations remain to be implemented. These relate mainly to competencies which are rightly the responsibilities of member states. So, for us to achieve our objective of having a strong pharmaceutical industry in Europe, we first of all have to look at how we can support each member state in implementing these recommendations in a manner that fits with their individual circumstances. *We believe that a key message to emerge from the meeting was that it is essential to make rapid progress in moving to put into effect the remaining G10 recommendations.*

9. One overarching lesson that has come from the G10 process, and from our own experience in the UK, is that it is important to work in partnership with the industry. *We would recommend that each member state should look to develop good working relations with the industry, and seek to better understand how the effects of government policy have a direct influence on the operations of business.* Governments need to understand better that industry needs a fair reward for innovation, and a stable and predictable market, which can be accessed fast, in which to grow. Having such a relationship helps governments and industry to understand each other's priorities, and to look at how they can work together better to help achieve the common goal of a thriving industry in Europe.

10. In creating a competitive environment there is a role for both the European Commission and member states to consider how new regulation impacts on the industry. We are not proposing that we should weaken any measures that provide protection to patients. *What we need to do is develop a regulatory system that maintains patient safety but does not place unnecessary additional burdens on the industry.*

11. The representatives of patient organisations who participated gave us a clear steer at the meeting that what is important to them is to have access to new medicines as quickly as possible, and that this should not be held up by reimbursement negotiations. We as governments have to look at how we can achieve this. Every member state has to manage its health budget. It is important that industry recognises that health budgets are finite, and that the cost of medicines has to be considered within this overall budget.

12. The G10 report recommended that reimbursement policies should not unduly delay patients' ability to have new medicines prescribed. Each reimbursement system is developed to fit within member state health systems. *We all need to look at our individual reimbursement systems to see how we can prevent delays in patients receiving medicines, and continue to support innovation*. We can first learn from the better aspects of the systems currently in use. It will not be a case of one system fits all, but we have to be willing to amend our current systems in the interest of patients.

13. There was a great deal of discussion about assessing the relative effectiveness of products within Europe. It is important to realise that we all have different health systems, and that one single assessment at EU level could not be made meaningful for all, or even most, member states. *To ensure that member states make decisions on relative effectiveness that are relevant to their health systems we should support a mechanism that allows sharing of information.* In the UK, we have a great deal of knowledge through the National Institute for Health and Clinical Excellence that we would be very happy to share with other member states.

14. The demand from patients for high-quality information about medicines and other treatment has never been greater. But in the era of the internet more does not necessarily equal better quality, and if people are to be empowered to make informed decisions in true partnership, then more needs to be done to raise standards and to increase the availability of objective, authoritative information to patients.

15. Statutory information provided with medicines should be of the highest quality and form the foundation on which wider information on medicines, disease areas and other treatments is built. Some progress has been made on this and patient involvement in the development of medicines information will be a powerful driver. But more needs to be done. Principles of good practice, tool kits for improving communication about healthcare issues – the sorts of issues highlighted by *Always Read the Leaflet,* the report of the Working Group on Patient Information – need to be adopted at a European level if we are to enable access to high-quality information throughout the Community.

16. *Further work is necessary on identification of best practice across Europe and how to ensure there is a levelling up within the European Union to the highest standards of information to patients.* This approach could build on the various models of public/private partnership in medicines information which already exist and how best use might be made of this potentially important means of developing high-quality, patient-focused information.

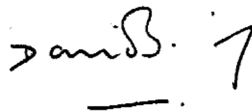
17. The European Medicines Agency outlined the work it is doing through its roadmap to encourage research and development. The steps taken by the European Medicines Agency include providing scientific advice early and introducing fast-track approvals. The latter is an important example of how the regulatory process can be streamlined without jeopardising patient safety.

18. We are currently negotiating the Seventh Framework Programme. This has important implications on how we can support research to develop medicines in Europe. In particular, the Innovative Medicines Initiative should increase the competitiveness of the European pharmaceutical sector by providing a co-ordinated approach to overcome the research bottlenecks in the drug development process, reducing drug development time and clinical attrition rate for new medicines. *The Innovative Medicines Initiative has the potential to improve Europeans' health and lifespan, and also offers a significant means of helping to achieve the goals of the Pharmaceutical Forum. The Innovative Medicines Initiative is a priority for the UK Government, and we would urge other member states to give it their urgent and strong support to boost the growth of the European biomedical science base.*

19. The commitment to the development of innovative medicines and the goodwill shown by the delegates at the event was impressive. We need to carry this forward into future fora, and the Pharmaceutical Forum in particular.

20. This report sets out both the wide range of issues raised by delegates as well as the UK identified key priorities. It captures the determination expressed by delegates to improve the research and development environment for pharmaceuticals in Europe, with the benefit this will bring to patients. In presenting it to the European Commission and member states we believe this report will prove to be valuable in setting out some of the major steps that need to be taken to strengthen the delivery of patient-centred innovation in medicines to patients in Europe.

Andy Burnham MP
Minister of State
for Delivery and Quality
Department of Health



Lord Sainsbury
Parliamentary Under-Secretary
for Science and Innovation
Department of Trade and Industry

Meeting Agenda

Delivering Patient-Centred Innovation in Medicines

Stationers' Hall, London – 1 December 2005	
09.30	**Introduction and welcome**
	Right Honourable Jane Kennedy MP, Minister of Health – UK (Chair)
09.40	**Why should the European Union want a competitive pharmaceutical industry?**
	Opening remarks: Lord Sainsbury, Minister of Science and Innovation – UK Richard Barker, The Association of the British Pharmaceutical Industry
11.00	**How can EU governments and industry work together to provide European patients with innovative and affordable medicines?**
	Opening remarks: Dr Franz B. Humer, President of the European Federation of Pharmaceutical Industries and Associations Hans Hoogervorst, Minister of Health, Welfare and Sport – The Netherlands – *How can Europe improve its environment for pharmaceutical innovation to regain its competitive edge?* • *How can reward for innovation be built into EU pricing and reimbursement systems while protecting healthcare budgets?* • *How can Europe improve its environment for pharmaceutical research and development?* – *How can the quality of information to patients be improved so that they are more sensitive to the benefits of innovation, more aware of quality-differentials, and more familiar with value in healthcare?*
12.45	**Pharmaceutical Forum**
	Heinz Zourek, Director General of Enterprise and Industry – European Commission
13.00	**Closing address**
	Right Honourable Jane Kennedy MP, Minister of Health – UK (Chair)
13.15	**Close**

The Round Table Meeting

This transcript records the many important points made by delegates during the discussions that took place at Stationers' Hall, London on 1 December 2005. I am grateful to my predecessor, Jane Kennedy MP, for so ably chairing the round table meeting.

Andy Burnham MP
Minister of State for Delivery and Quality
Department of Health

Transcript of the round table meeting

Introduction

1. Jane Kennedy (Department of Health, UK):

1.1 I am very pleased to welcome you to the United Kingdom this morning, in these splendid surroundings. We are here this morning in the Great Hall of the Worshipful Company of Stationers and Newspaper Makers. Obviously we are going to be looking forward as we move through our discussions this morning, but before we do, a little bit of looking back. This Worshipful Company of Stationers and Newspaper Makers is a very ancient guild here in the City of London. It found its first home in this area, but the original hall, which we are sitting in, was burnt down in the Great Fire of London in 1666 and replaced by the present hall, I am told, on the same site in 1673.

1.2 For those of you who are from the United States this may be of interest. The beautiful wooden screen on the south side, which is behind me, is the work of one Henry Ford, but I am sure he is no relation to the great Henry Ford of the Ford Motor Company. The wainscoting around the walls was finished two years later by Stephen College who was known at the time, and we are talking about 1675, as the Protestant Joiner, on account of his anti-Royalist pamphlet for which he was hanged at Oxford in 1681.

1.3 I thought you might be interested in just that little bit of history about the venue within which we are meeting, and I am enormously pleased that we are here this morning to discuss this very important subject. I am delighted that so many of you have been able to attend despite the time and work pressures that I know all of you face. I believe that the effort that you have made to be here today demonstrates the importance of the issues we are about to discuss.

1.4 In particular I welcome ministerial colleagues from across Europe. I am pleased to see that 16 member states and two candidate countries are represented here this morning. I would also like to welcome the European Commission to the meeting and hope that we can inform its thinking for the forthcoming Pharmaceutical Forum. I am also very pleased to welcome representatives from the three patient groups. I believe, if I may give you special welcome, your attendance here is significant in bringing to the table the views of the people who actually take the medicines that we are discussing.

1.5 I would also like to welcome representatives from the pharmaceutical industry to the table. While we are concentrating on European issues here today, we have to recognise that the

Jane Kennedy

pharmaceutical industry is global, and I am delighted to welcome representatives from the United States and from Japan, as well as those of you who are based here in Europe.

1.6 We have a large gathering around the table today and I suspect this is to do with the importance of the industry. My objective is to give everyone the opportunity to participate. A number of you have volunteered already to say a few words to start each section of our discussion. Once that is complete it is open for everyone around the table to input into the discussion. However, as there are so many of us, can I ask that interventions are through the chair, and I would be grateful if you would indicate clearly if you wish to intervene. Traditionally at these events, we use the plastic sign, but I will be watching so I will seek to catch your indication. I suggest that we try to keep interventions as brief as we can and to the point. It has been suggested that I ask for two minutes, but I know how difficult it is to keep politicians to two minutes, but I will be watching carefully so be warned.

1.7 That is the end of the formalities, so can we now move on to the substance of why we are here today, and that is to consider the environment for the pharmaceutical industry within Europe. In the UK we are proud to have a pharmaceutical industry that is truly world class. British laboratories have produced many of the world's most important and successful medicines. We have a very strong science base, and I am delighted to have Lord Sainsbury our Science Minister here with me this morning.

1.8 As we move into an era of new scientific possibilities, however, with advances in genetics and other areas, we will want to maintain that strong position through our support to science and research. I know that other countries represented here also have thriving industries, including some of our newest fellow members from central and Eastern Europe. Europe is the second largest market in the world after the United States, and whilst all of this could be seen as an achievement, I believe in Europe we do have to be realistic and look at the evidence, and we have to look at the trends that are becoming evident underneath the evidence.

1.9 Increasing investment here in Europe does not compare well with other world markets. You will have seen in the discussion paper how Europe compares to the United States.

Between 1990 and 2004 research and development investment in the United States grew 4.5 times, while in Europe it grew 2.7 times. My colleague Lord Sainsbury will describe further how Europe is losing ground.

1.10 What we need to do is to understand the reasons why there is a greater level of investment in the United States. The G10 came up with recommendations to address a number of these areas. There was broad agreement that the diagnosis was right, but only some of the recommended treatment has been administered. The work of G10 now needs to move to a new level, and it needs to deliver on its potential. I view the Pharmaceutical Forum announced by Vice-President Verheugen as a major opportunity to begin to reverse this overall trend. To some extent this process was started by Hans Hoogervorst, Minister for Health in the Netherlands, when he commissioned the World Health Organization to produce its report entitled *Priority Medicines for Europe and the World*, and I hope that Hans can share with us a little later some of the thinking coming out of that report.

1.11 To begin this process we must have commitment from all stakeholders to work in partnership. A strong partnership between all stakeholders is going to be essential if we are to make real progress, and to achieve this we all must understand what the pharmaceutical industry brings in relation to public health, and to the wider economy.

1.12 To begin this first part of the discussion and concentrating on why we should want a strong industrial base here in Europe, I call upon Lord Sainsbury to open the session by setting out the economic benefits of a competitive pharmaceutical industry. David Sainsbury is the Minister of Science and Innovation at the Department of Trade and Industry here in the UK, and with his family background in business he is well placed to introduce this session.

Why should the European Union want a competitive pharmaceutical industry?

2. Lord Sainsbury (Department of Trade and Industry, UK):

2.1 I am delighted to be participating in this round table discussion here today. The issues we are discussing are of vital importance if Europe is going to compete successfully on a global scale and also provide better healthcare for its people. This is of course not a new issue. Lisbon set us all the challenging target of making Europe the most competitive and dynamic knowledge-based economy in the world by 2010. It is essential therefore that we find a way to nurture those sectors that have the greatest opportunity to contribute to achieving the Lisbon agenda. That is what Commissioner Verheugen's strategy for the pharmaceutical sector sets out to do, and this is why the UK is hosting this presidency event here today.

2.2 The pharmaceutical industry is a key part of the high value-added knowledge economy and has a crucial role to play in creating its future health and wealth. The challenge is to make Europe a more attractive place for pharmaceutical investment. There has already been much debate on this subject, but the stark reality is that as a location for new pharmaceutical investment Europe continues to lose ground to the US, and more recently we have seen new challenges emerge such as India, Singapore and China.

2.3 There are two very clear danger signals. First, pharmaceutical research and development growth is slowing in Europe. Between 1990 and 2004 research and development investment grew 2.7 times in Europe, while in the USA it grew by 4.5 times. Europe's share of world pharmaceutical research and development investment fell from 49% in 1990 to 36% in 2001, while the US's share grew from 33% to 50%. Second, the proportion of new drugs originating from the US has now overtaken that from the European Union. According to the European Federation of Pharmaceutical Industries and Associations, between 2000 and 2004 Europe developed 57 new medicines, many fewer than the 88 in the period 1990–1994. Meanwhile the US produced 70 in 2000–2004 compared to 49 in 1990–1994.

2.4 If we fail to address this decline then we place in jeopardy a European industry that has contributed much to the health and economic prosperity of Europe. The industry employs significant numbers of Europe's most highly educated workers. It contributes 17% of all European Union business research and development. It provides over 5% of total European Union manufacturing exports, and creates some 3.5% of total European Union manufacturing added value. There are also the productivity gains that arise from healthier working populations.

2.5 In the new global knowledge economy it is vitally important that we strengthen the position of high value-added, high-tech industries such as the pharmaceutical industry, so what ideas can we come up with today to help push Commissioner Verheugen's new strategy? I would like to suggest three things.

2.6 First, we suffer from poor communication across Europe between the pharmaceutical industry and health ministries. We need a new partnership between producers and governments so that the needs of both can be better met. The Pharmaceutical Industry Competitiveness Task Force looked at market access, intellectual property rights, the regulations of medicines licensing, the science base, the clinical research and the wider economic climate. Nearly all of the 69 recommendations which it put forward have now been implemented, and both government and industry agree the process was, and remains, extremely valuable, a clear example of a win-win situation.

2.7 I was a member of the Pharmaceutical Industry Competitiveness Task Force and I learnt two lessons during its life. The first is that there is probably no industry which is more

Lord Sainsbury

impacted by the policies of government than the pharmaceutical industry. There are a number of obvious reasons for this. The first is, of course, that the customer is mainly the government, and related to that is all the pressure that we see across the world in terms of healthcare budgets. Secondly, health is, of course, emotionally a very sensitive issue and therefore there are huge pressures for regulation. The industry is hugely impacted by government policies and it is therefore critically important that the government gets those policies right.

2.8 The second thing I learnt is that there is no reason why the interests of the industry and health departments should be in conflict. In industry it is now seen more and more that competitive advantage can be created by companies working very closely and synergistically with its supply base, and I believe the same applies between health services and the pharmaceutical industry.

2.9 The second area where I believe we can make progress is in terms of supporting the science base on which the industry depends. The Commission has asked the European Federation of Pharmaceutical Industries and Associations to lead the development of a strategic research agenda for innovative medicines as one of the key technology platforms in the framework programmes. I am pleased that the industry has worked hard to identify the priority areas. Its plans focus on the long and expensive process of establishing the safety and efficacy of potential new drugs, and developing technologies and processes to reduce the time and costs of developing new drugs.

2.10 We are very pleased the industry is strongly taking the lead. We firmly believe they must do so to ensure the programme meets their needs and is user driven. The Innovative Medicines Initiative offers valuable potential to strengthen Europe's science base. One of the most exciting developments taking place in Europe today is the setting up of the European Research Council as a body which will support research across Europe on the basis purely of excellence, and on a peer review basis a council run by scientists for scientists. This will help us to drive up the very top level of scientific research across Europe in the same way that the National Science Foundation does in America, and of course this is very important because one of the reasons that we have seen some pharmaceutical

research go from Europe to America is to be alongside the really world-class top research universities in America.

2.11 Equally the setting up of the European Research Council has a second advantage, which is that we can make certain that the other research which is done in the framework programmes is properly user driven and is applied research dedicated to increasing the competitive advantage of Europe. I see the new joint technology initiatives across Europe as being a good example, but they do depend on industry being very clear about its needs and driving the whole process.

2.12 The third area where we need to look is the critical question of how sufficient reward for innovation can be built into reimbursement systems while protecting health budgets. Various ideas have been discussed within the European Union. Whatever the models in use or put forward there needs to be clear acknowledgment of the heavy investment companies make in research and development. In the UK model we seek to encourage innovation in branded medicines by making an agreed allowance for research and development wherever it is undertaken. Other key factors which we believe it is important to build into reimbursement models are predictability and stability, and it would be valuable today for member states to share their ideas and experience of schemes to incentivise innovation.

3. Jane Kennedy (Department of Health, UK):

3.1 Thank you David. I would like to open the discussion to the floor, and I would like to turn to Dr Richard Barker, Director General of the Association of the British Pharmaceutical Industry, to get the general discussion started. Perhaps Richard can share with us the benefits the industry can bring to Europe.

4. Dr Richard Barker (The Association of the British Pharmaceutical Industry):

4.1 Thank you Minister. I would like to welcome and expand on a few of Lord Sainsbury's points, not primarily from the industry's standpoint though. Dr Humer, the President of the European Federation of Pharmaceutical Industries and Associations, and others will do that better than I can, but as a former bioscience researcher in Europe and as a European, and I studied both in the UK and in Germany in past years, I think we need increasingly to think of these problems as Europeans.

4.2 The Lisbon ambition needs to begin to become reality because what future does Europe have but as a leading knowledge-based economy? Intellectually we all believe that, but why look to pharmaceuticals? I would like to give you three reasons: first, the twenty-first century will be the century of bioscience; second, we need the products; and third, we have a real chance of success.

4.3 Many of us see the twenty-first century as the century in which bioscience will flourish across the world, from new cancer therapies, to stem cells to replace ageing areas of the brain, but bioscience can only reach patients through the biopharmaceutical companies and enterprises. Typically we have a process that David Sainsbury referred to that takes those inventions from the laboratory to the medical school, often to emerging companies, and then largely to global pharmaceutical companies that have the skills in development and in regulatory approval. I think of pharmaceuticals, as I hope most of us do, as a sunrise industry in that respect, geared to the growth of bioscience.

4.4 My second point concerned our need for the products. You will have seen from today's papers in Britain that we are currently very taken up with the implications of the ageing population for our pensions. I would like to suggest that even more important than that are the implications of the ageing population of Europe for health. As Europeans we will need to work longer and in better health than in previous generations, so whether we are thinking of ourselves or our ageing parents, or our children and grandchildren, we can and must have innovation – innovation in heart disease, diabetes, Alzheimer's and viral disease. The list is endless. A critical point is that these treatments will add to our prosperity, not take away from it. We need to stop thinking of healthcare as a burden on the economy, but as an engine for growth. So pharmaceuticals will not be a cost to the system but will be a much more cost-effective way to treat chronic disease and to keep people out of expensive hospitals.

4.5 As Lord Sainsbury mentioned we have had a dialogue in recent years with the UK Government and the National Health Service about how the industry can partner to reduce the cost of long-term conditions and manage them more cost-effectively.

4.6 My third point was that we as Europeans have a real chance of success. Historically Europe has been the cradle of this industry but the last few years, as Lord Sainsbury said, have seen the US take over, and now we have the Asian giants knocking at the door. However, major European universities remain leaders in many bioscience fields, and we have the expertise to tackle some of these very tough problems in the lengthy, costly and complex process of bringing new medicines to market. This is still a very hit and miss process for which there can be very substantial improvements, and the Innovative Medicines Initiative (IMI) programme under the Framework Seven could make a real difference if we work together as Europeans to establish leadership in some of these areas.

4.7 Pharmaceuticals is still a leading sector in terms of research and development, high value manufacturing and exports, but as we have already heard, we now live in a world where global companies make global decisions. We have as Europeans, therefore, to give these companies positive reasons to invest here, and to create science-based clusters of innovation.

Richard Barker

4.8 Before taking this job I lived in Boston and in Boston you see leading bioscientists, medical schools, and small emerging biotech companies and global pharmaceutical companies working together as I believe we have never seen them working before. Here in Europe we have the ingredients and the ability to create these kinds of clusters of innovation if we think as Europeans and if we act with urgency. Thank you.

5. Jane Kennedy (Department of Health, UK):

5.1 Thank you Richard. Can I have an indication of those who might wish to speak. Whilst you are thinking I have the delegate from Finland. Can I perhaps then invite the patient organisations because they may have something they wish to contribute?

6. Ms Leila Kostiainen (Finland):

6.1 Ladies and gentlemen, the G10 process was designed to contribute both industrial competitiveness and public health goals. Often we see these two issues as a seesaw, either the environment is favourable to the industry or the medicines are affordable to the public. The challenge is to try and promote both at the same time.

6.2 Finland has welcomed the G10 initiative and feels strongly that the process should be taken forward. The renewed European Union legislation on medicines has now been implemented in Finland. These provisions promote access to innovative medicines, they improve the competitiveness of the generic market, and they improve pharmaco vigilance. However, the process should be taken further.

6.3 The issues taken up by the Commission are all well chosen. Relative effectiveness, pricing, reimbursement and information to patients are all important issues. All member states struggle with the task of trying to get better value for money, and with rising drug costs. Relative effectiveness is especially interesting for Finland. How do you relate the added therapeutic value of a medicine to its cost-effectiveness?

6.4 It is of vital importance to recognise what actions belong to the competence of the European Union and what actions fall within the competence of the member states.

Co-operation between states and working together in the field of assessing relative effectiveness is important, even though the final decisions are made by the member states. We will benefit from developing a common methodology for evaluating added therapeutic value of medicines and for carrying out pharmaco-economic studies. We are mostly authorising the same medicines and therefore the same evaluation and studies should not be unnecessarily repeated in each country.

6.5 A European-wide framework for evaluating relative effectiveness benefits both the pharmaceutical industry and public health. We must reward true innovation and not pay for a medicine that does not improve health but still creates costs. Thank you.

7. Jane Kennedy (Department of Health, UK):

7.1 Is there a patient organisation who wishes to speak? I invite Ms Sundseth from the European Cancer Patient Coalition.

8. Ms Hildrun Sundseth (European Cancer Patient Coalition):

8.1 Thank you very much. I would like to speak here on behalf of cancer patients. One third of the European Union population if you consider it over the lifetime will have cancer, and there is not one family in Europe that is not touched by cancer, be it somebody in the family, a friend or the surrounding neighbourhood. Cancer is a big disease and it is a devastating disease. Cancer patients are very anxious to have new innovative medicines because some of our present treatments are really cruel. We are waiting for new medicines and we want to get them faster, because this is often a question of life and death for some patients. Even one month can make a difference.

8.2 Let me give you an example, and I am sorry this is anecdotal, but it shows you the human element. One young cancer patient in our group survived because he was able to enrol himself in an early clinical trial and he is only alive now because he was able to do that. This was in Germany and this young man searched the internet and travelled from south to north Germany to get to the one institution in the one university where the clinical trial was taking place.

8.3 My plea is that from the patients' perspective it is so self-evident that we must keep innovation in Europe. As the example shows we also want to have the opportunity for our patients to take part in these early clinical trials. Thank you.

9. Mr Anders Olauson (European Patient Forum):

9.1 Thank you very much for the invitation to be here. I represent the European Patient Forum, which is an umbrella organisation for patients throughout Europe, and we represent something like 60 million people in Europe.

9.2 The initiative signalled here is very good, as is the new Pharmaceutical Forum that is going to have its first meeting shortly. From the patient perspective, we really look forward to this improving collaboration between industry, patient organisations and other stakeholders.

9.3 What I would like to emphasise to the governments here is that patients need to have access to medicines. There is not only the problem of developing new medicines, but also the one of patients getting access to medicines in Europe. I hope that this initiative, and the Pharmaceutical Forum, will find ways to solve these problems.

9.4 When it comes to research, I would like to speed up the process of reporting back to industry the experiences that patients have when using medicines. Getting this information quickly would help industry to improve existing medicines and to develop new medicines. Today the process can be very slow for many patients, including those suffering from cancer. I hope that this initiative, and the Pharmaceutical Forum, will find a way to improve this process. Once again, thank you very much for inviting the patients here.

10. Jane Kennedy (Department of Health, UK):

10.1 Next I invite the British Heart Foundation Patients Advisory Group and then I will look to an industry comment. I am sure there are many out there that have a lot to say.

11. Mr John Walsh (British Heart Foundation, Patients Advisory Group):

11.1 I would like to echo the thanks just given for inviting patients here, but I think the speaker from the European Patient Forum is too modest when he said he represents 60 million people. I suggest there is not one person in this room who would get through their whole life without once consulting a medical clinician. We are all patients, and he speaks, therefore, for the whole population rather than for the select few that people like I and he represent.

11.2 I would like also to follow what was said by the speaker from the European Cancer Patient Coalition. It is absolutely true that you meet individual cases in which patients are so eager to find a cure that they offer themselves for an unproven therapy. These are sad cases, but I believe they are evidence of the more general desire amongst all of us patients for some kind of speeding up of getting these drugs onto the market.

11.3 Against that, of course, a development over the last 20 years has been a growth in research into the retrospective metanalyses of the effect of drugs, and it is coming up with some rather surprising and in some cases disturbing results. That research maybe needs researching as there are a number of variables that I do not understand going on there, but to give you an idea of a recent example from my own area, there is a class of drugs called beta-blockers which many patients, including myself, are happy to take every morning with

their breakfast because they have a rather good effect on the heart of reducing its pulse rate and the pressure at which it works. They are very good drugs; however, surprisingly, the most recent research covering something like 50,000 patients over a period of ten years shows that these drugs are not having really much effect on mortality rates, which is why we take medicine, is it not, to live longer.

11.4 So you have to realise there is another side to the picture, but nevertheless I come down on the side of speeding things up, and the suggestion made by the Finnish delegate was both surprising to me and rather obvious when you think about it. If Europe purports to be a single market it should surely have a single approval mechanism for drugs should it not? Thank you.

12. Jane Kennedy (Department of Health, UK):

12.1 Dr Humer, you indicated you wanted to speak. I know we are going to be hearing from you after the break, but please have the floor now.

13. Dr Franz Humer (European Federation of Pharmaceutical Industries and Associations):

13.1 You seem to be anticipating many of the topics that I wanted to raise after the break, but I have a few comments on the speakers before me.

13.2 One of the great issues that we have and that we face as an industry is quick access to our drugs. If we simply look at statistics across Europe today – and let me quote one of them – 48% of drugs licensed between June 2000 and June 2004 were unavailable at the end of 2004 in most European countries. The delays from a central approval to marketability of drugs throughout Europe vary from 50 days to 450 days. We have a transparency directive which sets limits of 180 days, yet many of the governments across Europe ignore that, and the complaints from the patients organisations are very valid in that sense.

13.3 From an industry point of view it means that our drugs – and the medical progress associated with them – are not available when they could be available to patients. It also means that we are losing effective patent life, and therefore this reduces considerably the incentive to invest in research and development and that is a real serious danger.

13.4 The second point is health technology assessment, which the Minister from Finland raised. Again, I believe it is a very important and valid issue from several aspects – the government aspect, the patient aspect as well as from the industry aspect. But let us also make sure that technology assessment is not used, as it frequently is in Europe, to delay the introduction of new products, but that it helps speed up the introduction of new products, and that it is done at the appropriate time. We can only evaluate the real true value that drugs bring to society once they are being used widely in day-to-day life by the population. Our entire

Dr Franz Humer

price mechanisms which are in place in many European countries speak against such an assessment, and a fundamental rethink that hopefully we can take-up at the Pharmaceutical Forum is required here. Thank you.

14. Jane Kennedy (Department of Health, UK):

14.1 Thank you Dr Humer. My experience in the short time that I have had responsibility for this policy here in the UK has been a growing frustration amongst patients, and amongst the industry, with the difficulties with which the people who make the decisions about which drugs are going to be paid for put in the way of take-up of the medicine.

14.2 We have here in the UK a process of licensing and then further approval by the National Institute which is highly regarded. It is a regulatory framework which is respected and commands a lot of confidence, but nonetheless even after receiving approval from the National Institute of Health and Clinical Excellence, what we find is that there are still treatments and new devices and new medicines that our clinicians are still slow to use. This is a combination of a conservative approach by our clinicians, coupled with an anxiety of those organisations at a local level who now have the responsibility for managing the budgets about whether they can afford some of these new medicines, particularly those that have the high price tag attached, yet these are very often the very same medicines that patients groups, particularly cancer patients, are clamouring to be allowed access to.

14.3 These are very critical issues for us here in the UK and I am sure that it is the same across Europe, but just because they are critical issues it does not mean we should not consider what we need to do across Europe to enable our citizens to have the benefits of these new medicines, whilst at the same time doing it within a framework which we can afford.

15. Hans Hoogervorst (Netherlands):

15.1 Perhaps I could just make a couple of general comments. Let me first say that it goes without saying that the pharmaceutical industry has been one of the driving forces of tremendous health progress in past decades. If you talk about diabetes, heart diseases, depression or stomach ulcers, pharmaceutical innovation has played a huge role in

combating these diseases. Also the pharmaceutical industry has been a tremendous source of economic growth. European markets have grown tremendously and still have 35% of the world's market, although we have been overtaken by the US, and governments have done a lot to create these markets.

15.2 In Europe we insure practically everybody and medication is widely available to all our citizens – perhaps not quickly enough, but almost everybody in Europe can afford to pay for it. Still it is clear that despite the fact we offer this fantastic market to the pharmaceutical industry there seems to be a relative decline of the European pharmaceutical industry relative especially to the United States market. This worries me, not because the Netherlands has such a huge pharmaceutical industry but it worries me as a European citizen, and it also worries me as a Dutch man. I visited the New Jersey pharmaceutical industry in the summer and I saw way too many Dutch faces there, and of course that was very nice but I would rather have these people back in the Netherlands working for the Dutch economy. There is a tremendous brain-drain from Europe to the United States and what I found out is that even my American colleagues find this a very unhealthy development.

15.3 The main question is what is the main reason behind this brain-drain problem, especially to the United States? I believe most of it is the difference in the general business and academic climate in the United States which, let us face it, is more dynamic than the European business climate, and also the academic climate. We have a lot of academic excellence in Europe and it is very excellent at being academic, but it is not applied enough, and there is not enough co-operation with business.

15.4 We will have to do more to stimulate co-operation between academia and the pharmaceutical industry in Europe, and later on I will talk more on how we have tried to tackle that in the Netherlands.

15.5 Another matter of concern for the industry which I heard over and over in New Jersey is that we have a patchwork of regulatory systems. What I was told by the pharmaceutical industry in America was that of course we complain about pricing, but the main question is the segmentation of markets in Europe. We have to try to deal with that as it could be a very important issue for the Pharmaceutical Forum. Obviously for the time being regulatory procedures will be a matter of national policies, but perhaps we can do more to co-operate and to harmonise spontaneously our regulations and to speed up procedures, and in that I completely agree with Dr Humer. I believe those two things, more than the pricing issue, are vital to improve the competitive position of the pharmaceutical industry in Europe. Thank you.

16. Mr Haruo Naito (Eisai Co., Ltd):

16.1 I would like to talk about the health technology assessment. This is a very important area for the industry and once it is done merely for cost containment purposes this will kill the innovation. Drugs have their own characteristics so unified application of a model, or data selection may be not suitable to evaluate the cost-effectiveness and benefits of new medicines. Health technology assessments must be done very carefully otherwise it will have the potential to kill the innovation or the mind for innovation. Thank you very much.

17. Dr Klaus Schroeder (Germany):

17.1 At this point in this first round I do not want to make any comments as to how important the pharmaceutical industry is, and that we need innovative and high-quality products and that they need to be financed; this is a matter of course I believe.

17.2 I do not want to speak at this point about the dialogue we have in Germany with the pharmaceutical industry. We are a country of important pharmaceutical locations and in Germany we have started not just to involve patient organisations in advisory functions, but also in decision-taking processes.

17.3 In this round I want to say from a European perspective that we should look at the strategic decision we have to take, and there we do not just need to have co-operation between the governments and the industry, but against a strategic orientation towards biotechnologically produced medicines. There is also a possibility for co-operation between smaller companies and larger companies, and this should pave the way to set the decisions and the course for dedicated new medicine development. That is, I think, the opportunity for the future, so that in the future we will not lag behind other regions and other markets in this world.

17.4 The question we are facing right now is the policy problems and the research problems. How can you succeed under these conditions and put these new medicines efficiently on the market? Of course we have to be faster in the approval systems. We need financing ways and we need better financing of clinical research, but the important question will be how will we do this in Europe, and how will we handle the biotechnology aspect of the pharmaceutical industry in the future.

18. Professor Salvator Roberto Amendolia (Italy):

18.1 Thank you very much for the invitation to attend this event. The address to this conference from Minister Storace of Italy has been distributed and contains some analysis, and a few suggestions. The key elements of the analysis acknowledge, as everybody does, the gap vis-à-vis the US in the pharmaceutical sector; the lack of effective and coherent European policies aimed at boosting innovation; and the clear difficulty of industries investing in less

profitable drugs. The suggestions range from fostering research to improving price negotiation, and emphasise the need for better information to the public.

18.2 I would like to repeat here that Italy strongly supports the initiative of the Pharmaceutical Forum with the three European working groups on relative efficacy, prices and information to patients. Of the concepts which were outlined in the Minister's talk I would like to stress three or four of them which could be complementary to some of the things we have said. There is a need for harmonisation at the European level of the procedures to compare the innovation capacity of new and existing drugs, allowing, for example, a higher sale price for those drugs which are significantly innovative, and this has to be done keeping in mind that we have to favour access to drugs by the patients. This is a contradictory aspect which has been stressed at the beginning of the talk by the State Secretary of Finland.

18.3 In the Minister's address there is a proposal to set up an information system in each member state to make both the health professionals and the patients more knowledgeable of the diseases and of their cures, speeding up a rationalised use of the medicines. This could bring about a sort of European information card through a factual co-operation between public and private sectors and the European Commission.

18.4 There is a proposal to set up a technical organisation which acts at European level and assists the member states in their negotiations with the pharma industry about innovative drugs. We think this would be beneficial in fixing the prices and in comparing the costs of the pharmaceuticals.

18.5 Finally, at the national level, we need a definition of framework programmes between governmental institutions and pharma industries regarding categories of pharmaceutical products, not just single drugs. Competitiveness would be enhanced in terms of research and entrepreneurship, not just in terms of quality of health provided. This framework programme could offer the patients new therapeutic solutions in a shorter time, though being equally safe and effective.

18.6 So this goes together with the suggestion of having a common registration mechanism across Europe which would save a lot of time and money and would be beneficial to patients and doctors. Thank you.

19. Mr Ian Read (Pfizer):

19.1 Many speakers have discussed the issue of innovation and it would be useful if we could collectively start with a definition of innovation. It is very difficult if we confuse innovation as only being major breakthroughs. If we want to have a successful and robust pharmaceutical industry in Europe we have to find ways of supporting incremental innovation. In the process of drug development we all want breakthroughs and we all want

to get from A to D, but very often to get from A to D we have to go through B and C, and that needs to be financed.

20. Mr Per Wold-Olsen (Merck & Co., Inc.):

20.1 The point was made earlier that this industry is truly a global industry. I happen to be the representative for Europe in the global company Merck, and at the end of the day we have to make decisions in terms of investments and resource allocation between the US, Europe and other parts of the world. Science is moving forward which is good news, but whether it is in the institutions, in academia or within the pharmaceutical industry there is no limit to how far science will take us, and what kind of new medicines or new interventions we will see tomorrow that are not available today.

20.2 If we talk about Europe and its ability to compete, the point was also made earlier that there is probably no industry that sees more government interventions than this industry. Now if you put that together with the fact that decisions that we make today in terms of investments, and in terms of drug development and drug discovery, we will only get a return on that investment after 20 years. We need an environment that is predictable, and that tells you loud and clear that when the European Licensing Agency has signalled to you that the drug is approved it can be made available to patients, and it will actually be made available the next day, not a year later, two years later or three years later because of price and reimbursement.

20.3 Also, that you end up having a price that will stand to be the price for the life of the product, not one that is changed as a function of government intervention because the drug is too commercially successful, and every so often those interventions are driven off the cost base, not necessarily by what the benefit is to patients.

21. Jane Kennedy (Department of Health, UK):

21.1 Thank you. I am very interested to hear what the representatives of industry have to say. I know, because you tell me the frustrations that you have with the current processes, so I am going to ask Mr Lönngren from the European Medicines Agency to say a few words in a moment, but before I turn to him I am going to invite Mrs Lyngvig from Denmark to say a few words.

22. Mrs Jytte Lyngvig (Denmark):

22.1 Minister, thank you very much. As stressed in other interventions, we have heard about some of the challenges we are facing in the licensing process. These challenges have been underpinned by the introduction of new legislation. As a primary task, as the national agencies, we deal with risk/benefit analysis.

22.2 We very much welcome the introduction of the Pharmaceutical Forum. It is based on three substantive important pillars: pricing, patient information and relative effectiveness. In particular the pillar on relative effectiveness is important when talking about risk/benefit analysis.

22.3 I would also like to highlight another very important initiative from the European Commission, namely the Joint Technology Programme under the proposed Seventh Framework Programme.

22.4 As pointed out by the Dutch Minister, the most important part is that we work together – academia and industry. Regulatory authorities are linked to this as a part of the 'critical' triangle. If we do not continue to work for good European standards and in those ways make drugs acceptable, safe and affordable for all patients, we are not doing our work. So, we welcome these two initiatives very much, as long as they go hand in hand.

23. Jane Kennedy (Department of Health, UK):

23.1 Thank you for that. I often, when taking forward work in the UK, know that across Europe when we have a really good idea about how something can be improved we take forward that idea with great enthusiasm, but then when it comes to the United Kingdom, or to other nation states implementing the idea, sometimes in some way it does not quite work the way it was intended when the first good idea was thought of. I have a particular example in mind that I may share with you later, but Mr Lönngren from the European Medicines Agency might just say a few words.

24. Mr Thomas Lönngren (European Medicines Agency):

24.1 Thank you Minister. Let me explain the European Medicines Agency's role when it comes to innovative medicines. Up to now we have been operating for ten years and 60% of all innovative medicines that have been put on the European market so far have been evaluated by European Medicines Agency and approved by the European Commission. Now we have the revised pharmaceutical legislation that makes probably more of the innovative medicines enter the door to the European Medicines Agency, and hopefully also successfully come out with a positive scientific opinion for the Commission to grant authorisation. I believe that probably more than 90% of all the innovative medicines will use the centralised procedure. One application, one scientific assessment and one authorisation valid in 25 member states in the European Union – that is the future.

24.2 It is rather frustrating to work hard in order to do a scientific assessment in a very short time, and I must say that in the ten years of operation we have a very good track record. We have stuck to the timelines in 99% of the cases so we are not delaying any entry into the market of new innovative medicines in the European Union, but it is frustrating to see that patients cannot get access to these new medicines when European Medicines Agency

press releases have told them that authorisation in the European Union has been granted. This is an issue. It is not the competence of the European Commission. It is not the competence of the European Medicines Agency. It is the competence of each national government to deal with this.

24.3 Could I also ask if I can come back later in order to explain exactly what the European Medicines Agency will do in the future in order to improve research and development and access to medicines? I would prefer to come back to that later if I have that opportunity. Thank you.

25. Ms Maria Poncela Garcia (Spain):

25.1 I would like first of all to say that this forum is a very good idea because we are all the agents involved in this problem and we are all talking freely at this open table.

25.2 As Lord Sainsbury said, there needs to be very good communication between the Ministry of Health and the Ministry of Industry because there is conflict between the objectives of the two ministries. The Ministry of Health is involved in the control of the prices of the new medicines and has the objective of controlling the national budget for pharmaceutical expenditure. At the same time, the Ministry of Industry tries to create good conditions for this industry because of the Lisbon agenda. We think that this factor is strategic to obtain this target because without the pharmaceutical industry it is not possible to reach this target, especially in Spain where we are far from the target until now.

25.3 New medicines are not available to patients because the industry and the Ministries of Health and Industry are in discussion over prices, often for months. We are in discussions for so long because it is so difficult to establish the cost of the therapeutical added value of the new medicines. If we can solve this problem we could reduce the time it takes to make new medicines available for patients. So, as Finland has said before, from my particular point of view this is one of the crucial problems we have on the table now. Thank you.

26. Mr Arthur Higgins (Bayer HealthCare AG):

26.1 I would just like to build on the comments of the Minister from the Netherlands. I have the privilege of being the chairman of the Biotech industry in New Jersey and met many of his Dutch colleagues, but also many colleagues from all the countries present here today, and the lesson I saw in the US was two-fold. They really are challenging themselves when dealing with the industry whether at state level or at federal level: are their measures pro-innovation and secondly, are they patient centred?

26.2 The focus of this meeting is innovation so I would like us today to really honestly ask ourselves are our measures pro-innovation and patient centred? I believe that in partnership

between governments and industry we can come up with solutions that are indeed pro-innovation and patient centred, and not what they turn out too often to be: crude, cost-cutting measures which actually are against innovation, and are certainly not patient centred.

27. Mr Dorjan Marusic (Slovenia):

27.1 I am from Slovenia, so my position is that of one of the smallest European Union countries, currently only 0.5% of the European market, and with the average GDP the problem of introducing innovative drugs in Slovenia is one of the most important challenges.

27.2 Our proposal would be to establish as soon as possible a network of technology assessment which would help us a lot to upgrade our national protocol of safe implementation of new innovative and biological drugs.

27.3 The second proposal is that as soon as possible we should have a straight goal that will take into account the enlargement of the European Union market in sense of trying to establish a European Union price for all drugs. I know this is quite a challenging goal, but still we should start at least by developing some models to achieve that goal. Thank you.

28. Ms Aisling Burnand (BioIndustry Association):

28.1 I represent the UK Bio Industry Association and I also chair the National Association Council for Europa Bio. I just wanted to intervene and say that in representing over 1,500 bioscience companies across Europe what we really wish to see is that there is a friendly environment created for SMEs so that we can very much focus on the pro-innovation agenda and attempt to make that patient centric.

28.2 In order for that to happen there are probably four areas that are particularly important as have been highlighted by previous interventions: a streamlined and efficient, less burdensome regulatory system; looking at the clinical trial system; reviewing how we can improve timelines so that there is better efficiency, so that instead of it taking 15 years to get through the system perhaps we can it through in eight years. I know the European Medicines Agency has been making real progress but I do urge that we try and see how much further we can go, and to see what process engineering we can look at to improve the system, and to do that in partnership with the FDA.

28.3 Also, the uptake as mentioned is very important so that uptake is more efficient than it currently is right across the member states, because that is how the funds flow back into bioscience companies and allow them to fund further innovative projects in a range of areas, not exclusively, but many of them are involved in orphan medicines.

28.4 Lastly, the whole thorny area of funding is the one area where Europe very much lags the United States. A bioscience company that is aged between say six to ten years old will receive 16 times less funding than its US counterpart, and that clearly has an impact on how we can build in the future.

28.5 So, looking at new mechanisms whether it is at a European Union level or a member state level I would encourage. For instance, looking at the young innovative company status that the French have been implementing has some merit certainly for some countries, and looking at the European Investment Fund and seeing how they might encourage and support looking at more riskier ventures than perhaps they have hitherto invested in.

28.6 We welcome very much the European Medicines Agency and the fact they have introduced reduced fees for SMEs, and that sort of innovative approach certainly helps the SMEs. I would also urge member states to continue to look for fiscal incentives that might help support and bring private money into supporting the public money there. Those are some of the things that will really help the bioscience sector and make a difference in delivering medicines faster for patient benefit.

29. Jane Kennedy (Department of Health, UK):

29.1 Thank you very much for that and I think we are going to be coming on to talk about some of those issues. I am going to ask David Sainsbury to respond to some of the comments that have been made and say a few words before we close, but just before I ask David I have two delegates indicating they would like to speak.

30. Mr Thomas Lönngren (European Medicines Agency):

30.1 May I bring up a very positive example of how we could stimulate innovation and that is the orphan drug legislation. I have some interesting figures here since the legislation came into force in 2000. We have now 325 orphan drugs that have designation and the European Medicines Agency receives 80 new applications per year.

30.2 We have now 24 licensed authorised medicines for rare diseases reaching more than 1 million patients with rare diseases in the European Union. This is thanks to efforts by small and medium-sized companies, and also big pharmaceutical companies, to put research in orphan drug medicines. This is a very good example by the European small and medium-sized companies who have made a tremendous effort in order to get innovation to patients, especially for rare diseases, and this is a good example that everything is not negative.

31. Mr Jean-François Dehecq (sanofi-aventis):

31.1 I started with sanofi 33 years ago and in these three decades at any meeting I have never seen or heard someone not accepting that pharma is a key industry for Europe; that

pharma is not a new cost, but a strong limit for us; that we need partnership between government and the industry; and that we have to encourage research and development and so forth.

31.2 As we said this morning, this has been well known for 30 years, and with that we find a lot of partnership with many governments around the world in the three decades, but at the end of the day the only equation, which is the equilibrium of the social security system, was always solved by the same decisions – cost-cutting, taxes, delay for access to market and so on – and that is what destroyed the competitiveness of the pharma industry in Europe. So contracts are not respected – so a new Forum?

31.3 I think that if we are starting to make a new Forum, why not? We have the last one – G10 – when we spent a lot of time during three years with many ministers, and many people coming from stakeholders, and from the pharma industry, and we made a beautiful report and fantastic publicity was done by the Commission in many countries and so forth. All was done very well, but at the end of the day none of the 14 recommendations put inside this report was started.

31.4 So, yes, perhaps the Forum is something good, but only if we are ready to take even just a small step of action and not only step of words, and that is not easy. I think that for the second part of this meeting it is more important to try to find ways to make something than to again repeat that pharma is a very important industry for the European economy for the future.

32. Jane Kennedy (Department of Health, UK):

32.1 Thank you for that challenge to us, it is very much what I was thinking. I am going to ask David now to say a few words in response to what we have heard this morning before we close for coffee.

33. Lord Sainsbury (Department of Trade and Industry, UK):

33.1 I am going to make just a couple of points. The first is that the discussion was interesting and it did illustrate the wide range and scale of the issues which impact on the pharmaceutical industry, whether it is patents, orphan drugs, support for research, regulations or speed to the market. There is a huge range of subjects here.

33.2 The second point I would like to come back to is the point which was made by the Spanish delegate, which is that fundamental to this is that the ministries of industry get together with the departments of health because we again and again find that departments in the same country are going in completely different directions. There are some very practical issues where we can get a win-win situation for all parties involved, and again the point

was made that of course they have to be pro-innovation and they have to be patient centred, and again and again we lose this because we are trying to control budgets in a rather short, narrow basis.

33.3 I accept the point that this is not easy to do and we have not made a very good job of it yet across Europe, but that is no reason for not coming back and having another go at it. We have managed to do it in the UK. We got the parties together, and by people sitting down and talking about these very practical issues and not taking up political stances but actually dealing with these practical issues, we made an enormous amount of progress. Even having sat through a Competitiveness Council in Europe and a European Space Agency meeting this week, and with another one coming up, I still think it is possible to get people to focus on these practical issues if there is a win-win situation because at the end of the day we all have the same objectives. So, yes, a little bit of cynicism but actually you can make a difference.

34. Jane Kennedy (Department of Health, UK):

34.1 Thank you David. David and I actually are the best example of working together. We are like Siamese twins as we often appear at events of this sort together joined at the hip. I think it is of enormous benefit for us in the UK to have this close working relationship by two ministers who have very similar objectives in our portfolios. We have clearly a number of issues that have been raised.

34.2 One I had not thought of before was how the slowness of uptake might impact upon how much a medicine is reimbursed during its patent life. Another was the fact that the budgetary measures member states are beginning to take may impact upon innovation and the development of new ideas. There was the basic question, how do we define innovation?

34.3 There are many challenges that we have to face. I hope that in the next session, as we move to discuss the real needs of what we are hoping to make progress on this morning, we will begin to find some solutions and things that we can do that will make a practical difference to the working environment that the industry and our health services are operating within. Thank you very much.

How can European Union governments and industry work together to provide European patients with innovative and affordable medicines?

35. Jane Kennedy (Department of Health, UK):

35.1 We turn now to our second agenda item which is asking this meeting how can the European Union governments – how can we in government and you in industry – work

together to provide European patients with innovative and affordable medicines. That is the challenge and it is the crux of the matter that we now face. If we cannot manage to find a constructive way forward here we may find that our whole enterprise will fail, and I am immensely looking forward to hearing your ideas this morning.

35.2 I would now like to ask Franz Humer to give an industry perspective on how we can start to address the challenge of improving the European environment – to improve the competitiveness of the pharmaceutical industry. Franz, as I am sure you all know, is the President and CEO at Roche, and is speaking today as President of the European Federation of Pharmaceutical Industries and Associations.

36. Dr Franz Humer (European Federation of Pharmaceutical Industries and Associations):

36.1 Let me first of all say that this event is already proof that something is moving in the dialogue between governments, patients and industry, and I am very grateful the UK Government have called and organised this meeting and brought the people here together. I hope this meeting is not the last of this type of meeting but that we may be successful under the following presidencies to continue the dialogue on the one hand within the Pharmaceutical Forum, but also outside the formal structure of the Pharmaceutical Forum along a round table of this kind.

36.2 A number of the facts about the development of the pharmaceutical industry in Europe over the last years have already been mentioned, and I do not want to go over those again. One of the major concerns that we have is the fact that over the last few years we have very diligently worked together as a team with the Commission, the governments and the health ministers to develop the so-called G10 report and the G10 process with 14 different recommendations.

36.3 One of those is on its way to be implemented and that is the new pharmaceutical legislation which should have been implemented by the end of November 2005. There are some minor delays around Europe and there are a couple of major delays in the implementation of that legislation, and we as an industry will try to address that together with the Commission to speed up that process because this is extremely important to drive the efficiency of the regulatory process in Europe.

36.4 With regard to the other 13 recommendations we are a long way away from making progress. There are very few signs with regard to faster patient access. As I said before, the health technology assessment is primarily used in order to delay the advent of new drugs, and to cut the prices rather than having the objective of making a true assessment of the additional values that a new drug brings.

36.5 The industry is very prepared to work with all stakeholders in order to develop the dos and don't's of health technology assessment for and in Europe. We do not believe that it would be of advantage to have another centralised body across Europe to deal with this and to establish virtually global European prices, because frankly my fear is that those prices would be established at the lowest common denominator. Also, from a health technology assessment, how could we take into account different medical practices and different histories, different economic developments across the 25 member states?

36.6 My biggest worry – and there I share the view of my close friend Jean-François Dehecq – is that on the one hand we all have common objectives, but reality today is very different. Please forgive me if I mention a few examples. We have in a very large European market a reference price system which throws together patented and unpatented products, and as a result generic products increase their prices and original patented products have their prices decreased. I do not believe that this is an incentive for innovation.

36.7 We have in a number of countries totally non-transparent processes for health technology assessment, and in many countries the industry increasingly has the feeling that we are a lender of last resort because when budgetary gaps appear we very rapidly get unilaterally imposed arbitrary price cuts in a number of countries, north Europe as well as south Europe.

36.8 We feel Europe is at a crossroads in terms of defining what value we really want to place on innovation. We try to establish a few principles we would like to work on, debate and develop, to deliver a fair and appropriate reward for innovation and therapeutic progress, realising fully that innovation is not a sudden burst, but is a step-wise process that develops over many years.

36.9 My second point, which I alluded to in my first intervention, is that we need to secure early patient access to new therapeutic options as quickly as possible, and as quickly as the proof that medicines are safe and effective and manufactured to high-quality standards is given.

36.10 Thirdly we have today a system in Europe where prices of medicines are controlled by governments even if those governments and those health systems do not purchase, or do not reimburse these products. We believe we would make a major step forward if full competition were allowed for medicines that are neither purchased nor reimbursed by the state.

36.11 My fourth point is that we also need to focus on value and the appropriate evaluation of that value, and that evaluation needs to be carried out at the right time in a transparent, scientifically robust way with a goal of better healthcare, not with a goal of rationing.

36.12 We, as industry, also support better access for patients to information, and let me be clear that I am not talking here of US-style direct-to-consumer advertising. This is not what we are advocating, but I do not believe that it makes a lot of sense that European patients in different countries can access, via the internet in the US, information on products which is perhaps not always compatible with what has been approved in Europe, simply because we cannot currently communicate in the different European languages in the different countries with our patients.

36.13 On these principles the industry is very open and very constructive to developing a dialogue with all stakeholders. After a little bit of reluctance that we had because of the size of the Pharmaceutical Forum that has been called into life by Commissioner Verheugen, we have looked at it, we have discussed it with him and with his Cabinet, and we believe that this is a very constructive way forward. We will fully participate in that Forum, hopefully with the objective of two things: first, to deepen the understanding between the needs of the different stakeholders, but second, to really drive the implementation of what has been decided within the G10 process. It is not, it should not be, and it cannot be about reinventing G10. We should be driving the implementation of G10 because what we have decided three years ago is as valid today as it will be in the future.

36.14 Let me say one last word about supporting research and development. A very good programme between Commissioner Potocnik and the industry has been developed in the technology framework collaboration about developing concepts for pre-competitive research and that is, as I think you said before, research projects decided by researchers for researchers.

36.15 The industry is worried about the fact that we do not have a budget yet to implement and to get started, and only two weeks ago I heard from my American friends that the National Institutes of Health, the government and the pharma industry in the US are getting together to start a very similar programme. If they start early they have headway. If they have a long headway Europe will again come in second, and we do not need to come in second. I am a convinced European, but I do have a responsibility for a global organisation and I hope we can, through events like this and through events like the Pharmaceutical Forum, get our act together to bring this industry back where it should be: the leader worldwide in bringing new and better products to the patients of Europe, and the world. Thank you.

37. Jane Kennedy (Department of Health, UK):

37.1 Thank you very much, Dr Humer, for that very interesting and thought-provoking presentation. I referred earlier to the work that the Netherlands had carried out jointly with the World Health Organization during their presidency of the European Union. Their work looked at ways of encouraging investment in research and development in disease areas where we have seen little development in recent years. I am going to call on Minister

Hoogervorst, Minister of Health in the Netherlands, to say a few words about your *Priority Medicines* report.

38. Hans Hoogervorst (Netherlands):

38.1 It is almost a year ago when indeed the Netherlands was president of the European Union that we organised a high-level conference in The Hague on the topic of what we call Priority Medicines. The topic under discussion was a report by the WHO commissioned by the Netherlands Government which was drafted for this conference with the title *Priority Medicines for Europe and the World.* This report was essentially a proposed agenda for pharmaceutical research and development from the perspective of public health, and taking part in the conference were representatives from the pharmaceutical industry, patient organisations, scientific research institutions, as well as the European Investment Bank.

38.2 Among the reasons for organising this conference and commissioning the preparation of the report to the WHO were the debates around the G10 proposals concerning the future of the European pharmaceutical industry. The idea was that formulating a public-health-based agenda for research and development in pharmaceuticals could help to provide focus to the Seventh Framework Programme of the European Union when it comes to the important area of pharmaceutical innovation. One of the findings, after all, of the G10 was that public-health-oriented pharmaceutical research stimulates innovation and can contribute to the competitiveness of the European economy, and in this way we can implement the sustainability dimension of the Lisbon strategy.

38.3 The method used by the WHO in the Priority Medicines project was very impressive. They took the following steps in its research. First, they made a measurement of the burden of disease in Europe and the world as a whole, and then they very carefully scrutinised which pharmaceutical solutions for these diseases are currently available, or more importantly are not available. In doing so they were able to identify what they called the so-called pharmaceutical gaps, big disease burdens for which there is currently not a sufficient pharmaceutical solution – and they made a prioritisation of the pharmaceutical gaps that need to be filled by pharmaceutical innovation.

38.4 The WHO was successful in involving all major stakeholders including industry in its project and in setting up the list of priorities, and that really helped to make the conference draw conclusions. What were those conclusions of the conference? First of all – and it is perhaps a little bit of a truism but truisms can be very important – there was a pressing need to develop a comprehensive and coherent agenda "that brings together research and industrial interests within the general framework of public health".

38.5 Second, for this research agenda a number of key areas of interest were mentioned, and those key areas included first, the need for new antibiotics to attack the rapidly growing

Hans Hoogervorst

problem of multi-resistant bacteria which is truly a very big problem in our societies; second, to prepare solutions for the effect of pandemic influenza (and we seem to be talking of nothing else these days but it was still new at the time); third, to create better and more effective prevention and treatment for diabetes and HIV Aids, and also there was special attention needed for drugs that are specifically made for elderly people and children which is currently not sufficiently the case. Lastly, there is the need to reduce barriers and time lags in the process of market admission of new pharmaceuticals which has been referred to many times this morning.

38.6 Most of these key areas are important for the developed as well as the underdeveloped parts of the world. For underdeveloped countries some additional conclusions were drawn on priorities, for example the need to develop new and better treatment of malaria, and secondly to create and produce heat-resistant variants of existing drugs, for example insulin.

38.7 What will be the follow-up to this conference? Last week at the WHO Head Office in Geneva there was a follow-up conference on the Priority Medicines issue, and the participants in this meeting, including representatives from the European Commission, agreed that it would be valuable to keep the case for priority setting for research and development of pharmaceuticals on the agenda, and to make regular updates of the WHO report.

38.8 I am convinced that it will also be valuable to link the outcomes of the priority-setting process to the efforts that the European Union hopefully is going to put into strengthening research and development of pharmaceuticals, which means through the Seventh Framework Programme and the Innovative Medicines Initiative, which are both under construction at the moment.

38.9 Of course there is also room for manoeuvre for the individual member states. In the Netherlands we are going to have more than a modest example of this. I would like to mention the decision recently taken by the Dutch Government to step into a public/private partnership with universities and a number of pharmaceutical firms with the goal of

boosting pharmaceutical research and development in not all but some of the areas mentioned in the *Priority Medicines* report. This project is going to be called the Top Institute Pharm and the Dutch Government will invest €130 million into this project for the next four years, and the other parties involved will at least spend the same amount of money on this project.

38.10 It is, of course, not easy for us to compete with the huge amounts of money that the United States spends in pharmaceutical research through the National Institutes of Health, since deficit spending seems to be less of a problem there than here, but if we add up all of the current efforts and those under design in the European Union we should be able to get somewhere and create positive results. Indeed, I am certain that Europe does not even have to spend the same amounts of money as the USA to be as effective, as long as we do it intelligently. Thank you very much.

39. Jane Kennedy (Department of Health, UK):

39.1 Thank you very much Hans. I am about to open up the discussion to everyone. We have heard already not only the examples there from the Netherlands as to how deliberate steps can be taken to encourage research and development, but we have also heard from Franz Humer with a series of requests for us to consider, for example an appropriate reward for innovation, securing early patient access, full competition for medicines that are not purchased or reimbursed by the member states, and the possibility of a Europe-wide research and development fund. I know that these are probably not new ideas. I estimate that these are suggestions that industry has been making in the European forum for some time, and I want to open up the discussion now to everyone to respond to that. However, if I can just set it in this context.

39.2 When Vice-President Verheugen outlined his vision for the Pharmaceutical Forum he highlighted three areas that he believed it should look at, the first of which was pricing, the second of which was relative effectiveness, and third was the question of information to patients. Now maybe we could begin and frame our discussion with those three ideas. I know that it will not be difficult to get people to contribute on the issue of pricing and reimbursement issues. They are rightly national competencies and they are for each member state to determine. The G10 report highlighted areas that might be improved such as ensuring reimbursement discussions do not delay entry to market of products and that there should be full competition for medicines not reimbursed by member states. I realise that this area in particular, however, can be very emotive, but it is one that Vice-President Verheugen wishes us to consider, so I am going to ask Andrew Witty in a moment to comment, but first the delegate from Sweden, Mr Olsen, who has already indicated he wants to speak.

40 Mr Hans Christer Olsen (Sweden):

40.1 Thank you for the opportunity to participate in this very important meeting. I am replacing the Swedish Minister of Industry, Mr Tomas Ostros, who has asked me to convey his personal apologies for not being able to participate today. This is because we are just in the very late stage of preparing an action plan for the life sciences industries in Sweden, and that includes the pharmaceutical, biotechnology and medical equipment sectors. It was the original intention that this action plan should be presented by him in Stockholm today, but there is now a delay of a few days, and hopefully we will be able to do it next week.

40.2 In my country, as in many others, we see many good reasons and opportunities to encourage research and industrial exploitation of results in medicine and biotechnology. Looking back we have a very long tradition in these sectors of both applied medical research and of industrial development, both in close co-operation.

40.3 We believe that one of the key factors for success is the opportunity for close co-operation between academia and industry. We believe it has played an important role for many of our outcomes, both in the form of products but also industries working in areas like pharmaceuticals, diagnostic tests, pacemakers, titanium implants etc. There are many other examples.

40.4 Today we estimate that there are in Sweden some 800 companies which have their core businesses in these areas which are referred to as life science industries. We can see large potential for further growth within these areas, but of course there are many issues to tackle which today's discussion demonstrates.

40.5 This is one reason why we are in the final stage of developing our national action plan for this sector, including the areas I just mentioned. It is clear that we have been inspired by our British colleagues at the Department of Health from their early focus and pioneering work in this sector. Also our participation in G10, the European Union's high-level group, has served as an inspiration for the development of our national programme, and of course we look forward to the latest initiative and the work being planned by the Commission for the Pharmaceutical Forum. Thank you.

41 Jane Kennedy (Department of Health, UK):

41.1 Thank you. I am going to ask for an industry point of view now and I am going to ask Andrew Witty from GlaxoSmithKline if you would like to say a few words.

42 Andrew Witty (GlaxoSmithKline):

42.1 Thank you Minister, I appreciate the opportunity. We clearly have an opportunity now through the high-level forum for a renewed dialogue between industry and importantly

member states, catalysed by the Commission, to try and make some real progress. We need to make progress on implementation of the G10 recommendations. They are agreed; they make sense across the board, and they need to be implemented. That is obvious and something we should all focus on. But we also need to make progress on addressing the much more fundamental set of issues around pricing and reimbursement across Europe. It is pretty obvious that almost nobody is satisfied with the current situation on either side of the table.

42.2 In a sense the price negotiation that exists across every product and every company and in every member state, really is the crucible of all of the tension between the providers of healthcare and medical solutions and the purchasers of healthcare and medical solutions. Of course the irony is the debate that takes place on price, or the price negotiation which determines the future earnings for the companies, and of course the liabilities for governments, takes place when we have absolutely the least knowledge to make a good decision. It may be the case that we have researched the medicine in only three or four thousand patients, maybe only in a very strict clinical trial setting, or maybe never in the member state community, and certainly not within a real environment. So the notion that the future financial relationship, and the future incenting relationship of this marketplace, is determined in such a high pressurised environment, with such little knowledge and data, really is something we need to start to focus on and address as a potential way to release the tension in this relationship.

42.3 We need to think about mechanisms – and the Forum is an ideal opportunity – to bring medicines quickly to market, to be able to start to demonstrate the data which you can only achieve once the medicine has been used in real clinical practice, not in a clinical trial, and to then determine the true value of the medicine. That implies that prices might change post-launch. They already change post-launch, but only go downwards. For the future we need to think about an environment where prices can go up as well as down, as innovation is either demonstrated or fails to be demonstrated, but in a context where we are making a decision with better information based on a much better real-world experience in the relevant member state, and at a time point when we have had the time to really understand what we are dealing with. Those sorts of opportunities are things that the member states and industry should start to talk about now, because at the moment we are creating too much tension in a piece of the system, and really the results are obvious to all of us – neither side is happy.

42.4 The second area which we need to be very thoughtful about is that clearly this is a unique marketplace in many regards. It is a highly managed, monopolistic marketplace, in most cases with one single purchaser. It is a marketplace where the provider relies on ultra-long cycles of investment and innovation to deliver the products that patients want. At the same time we manage that market linked to, for example, the generic marketplace, which is a

completely different marketplace, and we need to start making some choices about what we want to incent in the member states.

42.5 If we want to give incentives for developing truly innovative medicines, then the way in which we price and we negotiate, and the way in which we allocate resources, needs to be targeted in that direction. Because at the moment, by having in almost all member states hard or soft linkages between off-patent medicine prices and on-patent medicine prices, effectively that sends a signal that the priority is not innovative medicine at all, and actually you see a cross-subsidisation effect going on across from the innovative to the non-innovative medicine. Now we have the opportunity to release substantial funding. We clearly have the opportunity to release a different mindset of thinking around innovative pricing.

42.6 Within all of that a focus on value obviously makes much more sense than any of the other bases for coming up with prices. What patients, and I think governments, fundamentally want is medicines which deliver the most value to the patient and the system. How do you do that? Clearly health technology assessment helps, but it cannot be done pre-launch, it has to be done post-launch, and it has to, in my view, be done in the member state where the drug is going to be used, because the economics and the medical practice of all the different member states are very different. The notion of a common set of European principles to ensure that there is a level of transparency and we do not end up with 25 completely different sets of questions to answer makes perfect sense, but the notion of a single bureaucracy which somehow comes up with an average value creation is economically impossible. We need to make sure that we try and tread a very careful line between those two different pressures.

42.7 Fundamentally this meeting, and the high-level Forum, really does offer us a chance to move forward, but I suggest that what we have to start doing is making some choices. The choices are not easy choices. If the priority is that we want to deliver innovative, valuable, safe, effective medicines to patients with serious disease, we need to start aligning our systems, price policy and approaches, and be prepared to make some substantial changes. My guess, if we went and asked most patients what they would choose, is that the answer is pretty obvious. I appreciate the opportunity to comment.

43. Jane Kennedy (Department of Health, UK):

43.1 Thank you for that and I agree. I was going to say that we have talked about the two sides of government and industry, but actually patients are the ones in the forefront demanding access to these new medicines. Are there other people who wish to contribute?

44. Dr Fernando Bello (Portugal):

44.1 Thank you madam. As you know I am representing the Minister of Health who was not available because of a heavy schedule in Lisbon. He thought it was mandatory to be represented at such an important event.

44.2 The problem has been evoked by many people around the table of how to have a competitive and effective pharmaceutical industry in Europe. The Lisbon agenda has been also evoked many times. It is a very interesting document but the problem is not the content of the document; the problem is how to effectively implement the Lisbon agenda. Franz Humer mentioned something that in our opinion is very important. Europe is at a crossroads, and the representative of GSK said something complementary, which is that we must look at the problem with a different mind-set. If you are convinced that Europe's and its pharmaceutical sector is at a crossroads, we are facing a shift in the global environment, and how to solve it is a simple problem of choice and decisions. We must make the appropriate choices and we must implement the choices we think are effective.

44.3 Let me convey what we are doing in Portugal. The Prime Minister decided that the pharmaceutical industry is considered a strategic asset for the future of Portugal and he decided that it was necessary to forge new alliances at the governmental level, and that is why in what concerns the pharmaceutical industries we have now the Minister of Health, the Minister of Science, Technology and Higher Education, and the Minister of Economy and Innovation under the supervision of the Prime Minister collaborating closely together.

44.4 We have tried successfully to open effective communication channels with industry to improve the dialogue and to understand mutual objectives and promoting this kind of dialogue in an effective way. We must encourage good partnership between industry and the scientific community, but to be successful Portugal developed a very effective and coherent system for incentives – a very large panel of incentives – to stimulate the opportunities for successful co-operation between the different partners.

44.5 We think that this effort must be promoted at the European level and that is what we expect from European authorities. Thank you.

45. Jane Kennedy (Department of Health, UK):

45.1 Thank you for that example of some work that is being done within one country that will make a difference. One of the recurring themes that I am hearing is the need to improve communications. That is clearly very important and a number of us are taking real steps to do that, but I also am very conscious that it is not going to be enough to simply 'talk the talk', to use that common American expression. It is going to be very important that we also 'walk the walk' and make the changes that are actually going to make the difference

to the competitiveness of Europe as a market for the development and innovation of new medicines and new ideas. Does anybody else want to talk about pricing?

46. Mr John Papathanassiou (Greece):

46.1 I heard one of the topics about full competition on medicines which are not purchased to be reimbursed by the state. I am for full competition but under the condition that the consumer can decide with the very specific and clear theory of what he wants he can buy. The question is whether the medicine is one of these products. Even if we give the necessary information, which is also a point which has been mentioned, can the person who needs the medicine decide by himself? Can he judge with this information what he can use or not? We have the interference of the prescription of the doctors and the problem is whether they prescribe without any influence what is best for the patient.

46.2 If we want full competition to be applied in this sector, we have first to guarantee that the whole system will work that way, because otherwise full competition cannot guarantee that the end user, who is the patient, will decide with the right criteria and is not depending on others who decide for him because, practically, the doctor is a very important factor.

46.3 Furthermore, there are differences between countries. There are countries where the healthcare system does not work in that way so that the total population, or a big majority, buys all the drugs through the healthcare system, not because they do not want to pay less of course, but because the system is so bureaucratic and so complicated that a lot of people are obliged to buy directly. So, we would put them in the situation that they would operate in a completely free market, not because they would like to do so, but because some countries have problems, which they first should overcome, and then they speak or even think about such a free system and full competition in that area.

47. Jane Kennedy (Department of Health, UK):

47.1 Thank you for that comment. It strikes me that actually, as was said almost at the outset of our discussion, this industry is one of the few industries that is very much hit and influenced by the regulations that we in government put in place, precisely because the consumer does not have the ability to be the only person making that choice. Very often, particularly if you are talking about the new medicines for the treatment of cancer, for example, they are superb at what they are designed to do, but the patient clearly needs to be supported in coming to the decision that there is a particular medicine that they need to take.

47.2 So, we are talking about an industry that is working in an environment unlike any other, and we in government have enormous responsibility to make sure that the regulation of that industry, so critical to patient safety and to the quality of support that we give to

patients, is a regulatory framework which is robust, protects patients safety and ensures quality, but also allows innovation and encourages innovation, and allows the ready access of patients to those medicines. We have a clear responsibility to two different sets of people with different pressures upon us as we consider those responsibilities, and that is a very important point that you have made.

48. Ms Hildrun Sundseth (European Cancer Patient Coalition):

48.1 I hope that my contribution to the issue of pricing is relevant. I wanted to say that patient groups are actually aware of national healthcare budgets. We are painfully aware of that. We are also aware that when we argue the case for cancer – "You must do that for cancer patients and we must have that medicine" – that since the budgets are clearly defined and finite, we may be taking resources away from another group. Patients across Europe, in our Coalition anyway, are very much for solidarity and that everybody must have their fair share of access to medicines and healthcare.

48.2 I have heard a lot about the regulation that is involved. Is this all necessary? Certainly a robust protection of the patient's safety is very important, but as for all the pricing and reimbursement regulations, what does that bring us really from the patient perspective? I hope I am not jumping ahead, but as Lord Sainsbury mentioned this morning, we have to create win-win situations.

48.3 We have to move forward and perhaps you will allow me to think a little bit out of the box here and say that as I understand it in the cancer field there are about two new innovative cancer drugs that come to the market a year and they are mostly given in a hospital setting. This is where we have in most member states the biggest structural difficulties funding these medicines.

48.4 So could we not consider a sort of European Union pilot where we say these medicines are actually for exceptional circumstances, heavily disabling and life-threatening diseases, and agree on a specific procedure for these medicines, centrally approved by the European Medicines Agency, to be immediately available to the patient in the hospital setting across Europe.

48.5 As Mr Witty mentioned, the pricing negotiations can come later on after one gets the experience and collects the data during this period (not beforehand) on the effectiveness of this medicine in a controlled hospital environment. Then you can make better decisions about the value of these medicines and the price of them.

49. Jane Kennedy (Department of Health, UK):

49.1 Thank you very much for that. In England and Wales the National Institute for Health and Clinical Excellence considers a new medicine to confirm its effectiveness and cost-effectiveness. We have said that within three months, once it has received National Institute for Health and Clinical Excellence approval, primary care trusts, the organisations that pay for the medicines, must provide funding for the medicines. However, it still does not happen in all cases and we have to ask the question do we even need the three months? The three months was there to allow them to organise their budgets, but I think we need to consider whether we even need the three months. I have Bayer and Merck who both wish to comment, and then I will come to Finland.

50. Mr Arthur Higgins (Bayer HealthCare AG):

50.1 Our colleague from the cancer association really in some ways addressed what I was a little concerned about from the Minister from Greece. We are talking about products that are at an approval stage and it is a question of getting access, and again, not speaking as a representative of a pharmaceutical company but as a consumer and a patient, I feel I should have the right to get access to that product if it is not getting reimbursed in the system.

50.2 It is a very dangerous assumption that governments are better placed to make that decision than patients, and we have to be honest with ourselves as to whether it is really the patient we are protecting, or are we concerned that by some people having access to these medicines that we will then have the political debate about why the medicine is not available to a wider population. Again, I ask is it really patient centred, or is it politically centred?

51. Jane Kennedy (Department of Health, UK):

51.1 Minister Kostiainen from Finland.

52. Ms Leila Kostiainen (Finland):

52.1 Thank you Minister, for the possibility of a short comment. I fully agree with Mr Witty from Glaxo in the fact that we can evaluate the drug fully only after it is in wide use. That is true and it is a very interesting idea that we should decide the real price of a drug only afterwards. It is also very obvious that by this means the price could go down but it also could go up. That is very interesting, and I think it means that the rewarding of innovation would come after the new medicine has proved to be very good and proved to provide improvement. The idea is worth considering.

53. Jane Kennedy (Department of Health, UK):

53.1 I want to make sure that everybody that wants to has an opportunity to speak on this really important issue.

54. Dr Klaus Schroeder (Germany):

54.1 Madam Chair, I would like to make two comments, one brief comment on pricing and a second comment on information policy.

54.2 As regards pricing I would like to report about a change we had in Germany. In January 2004 we amended a legal act and for all non-prescriptive drugs that were reimbursed we freed the prices in the pharmacies in Germany. The development was not as strong as some people had expected. Maybe this is due to the German mentality that maybe they think drugs are like stamps, and that when they buy their stamps they do not haggle over the price of the stamps so they do not seem to haggle over the prices of drugs.

54.3 We did more, we allowed buying it from abroad by pharmacies and actually we did not experience such massive movements as industry had predicted. However, I am very optimistic and I know that sometimes it takes longer for people to change their behaviour and for people to take on more responsibility, and maybe also for buying drugs which are available in German pharmacies. Maybe the reason also that it has not developed differently is that the German pharmacists play a role here.

54.4 In this context, and this now concerns my second comment on information policy, Dr Humer mentioned that in a very specific form and I think that is good. We do not want an American strategy. I am convinced, and let me give you some reasons for it, that an American strategy would be the wrong way for us. An innovative, good medicine only fulfils its purpose if there is compliance at the end, if the patient uses the medicine as it is indicated, and for this we need good and well-informed doctors.

54.5 If we take the role of patients, and this point is important, then we need quality assurance and we need information that is assessed by independent authorities as to how information is handled. In Germany, because of the change we had in our law, we allow that all technical information that comes with approval and has the test of approval is available. You can get that from the internet and from other sources.

54.6 What we do not want, however, is to have advertising for prescription medicines, but we believe it could be a good way to take this quality assured information, that maybe industry could use this in such a way as we do in other areas for consumers. For instance, if there is a product, why should industry not point out that our product is particularly well assessed and has been clearly well evaluated? Why should that not be possible? If we embark on this way

then I think this lies in the interest of the patients as well, because we want the patients to take a more explicit role, they have to decide explicitly and consciously, but for that they need to be able to inform themselves. Therefore, I agree with Dr Humer, we should not have public advertising or consumer advertising, but we should try to get informed patients and still promote and optimise the dialogue between patients and industry.

55. Jane Kennedy (Department of Health, UK):

55.1 Thank you for that comment. I want say one thing on advertising. We in the UK relaxed the restrictions on TV advertising and on advertising for certain medicines and it has had a very beneficial effect.

55.2 It is interesting when you see how companies do advertise, and you say we should not be permitting advertising of prescription-only medicines. Here in the UK we have seen an advert from Phillips, the electronic company, and they advertise their latest innovative mobile phone which acts as a phone and a camera, and a diary, and cooks your breakfast for you or just about. The other product that they advertise in the same advertisement is a MRI scanner, and when I watch that advert I think, "What would I do with that for Christmas!" It is on general public advertising, so it an interesting approach that Phillips has taken, and your comments there prompted me to think of them. It just shows you that advertising does work.

55.3 Can I ask Richard Pilnik from Lilly just to say a few words about the overall research and development environment in Europe. This is one of the areas that the European Commission wants us to identify how we can improve the environment within which the pharmaceutical industry is operating.

56. Mr Richard Pilnik (Lilly):

56.1 Thank you Minister. Maybe the best way to describe it is to bring it down to a very practical level and describe what I go through representing Eli Lilly's interests and commitments to research within the European environment.

56.2 It was interesting to see a few weeks ago a report in the *Financial Times* using data from the Department of Trade and Industry looking at all of the industries and their research and development as a percent of total sales. They looked across all of the industries, and in fact they even outlined certain companies within these industries, and it was very evident that the healthcare investment in research and development far outweighs any industry that you can pick on in terms of their commitment to research and development. That is going to continue, and it is going to continue for very good reasons.

56.3 First, it is going to continue for the healthcare of patients, and secondly that need is only going to increase when you think of this freight train of ageing population that is coming our way that is going to need more medications for cancer, for hearts, for diabetes and so on.

56.4 In our case we have four research centres in Europe. We have a neuroscience centre, we have an endocrinology centre, we have a chemistry centre, and we have another centre that prepares materials for clinical trials, and this is all research and development. Now, where we have continued to invest I notice that I need to spend a lot more time with my senior management at our corporate headquarters justifying why we should continue in this region when quite frankly the environment and the opportunities in Asia, Latin America and North America are always drawing and are getting better. So clearly there is a need there. The commitment to research and development will continue, but the environment in which to do that research and development is where we really need to protect and think about in terms of the opportunities for Europe.

56.5 I take this opportunity Minister to ask you to try, when you bring this to a close, to have a call to action from everybody here as to how we now take from this discussion a practical step forward. One way we could do it is the Innovative Medicines Initiative, an initiative which is enthusiastically supported by the industry and yet only half of the member states have committed to that. That is something that really is a co-operation and a partnership to promote and further research and development in this region. It may also be a way to recapture a lot of the brain-drain that has now left, and there are a few member states here that are initiating ways to recruit their PhDs back to their home countries. We need to find more ways of being able to bring back that talent.

57. Jane Kennedy (Department of Health, UK):

57.1 Thank you for that, Richard. Does anybody want to comment on what you have heard so far?

58. Mr Haruo Naito (Eisai Co., Ltd):

58.1 I am probably the one person here from the Asian region and I would like to speak about the European Union around the competitiveness issue. We are an industry which lives on innovation, and innovation centring on its use for patients. Joint efforts to make innovation available to the patient is our responsibility, and in this regard the balance of health policy and industry policy is key. Mere cost containments kill the mind of innovation. We all need innovation in pricing as much as possible, and intellectual property protection and data protection is also keenly important.

58.2 My second point is that innovation depends on people. Intellectually strong scientists' contribution to patients through drug discovery; position of cutting-edge scientific and technological background; ability to motivate others, and also serendipity – luck – are very important parts of the innovation. Those common characteristics of innovative people we like to find in the European Union.

58.3 Cluster is also very important, and Richard mentioned clusters among industry, academia and medical institutions, because the speed of information inside the cluster is fast, and also good people interact and create knowledge in the cluster, and therefore the success rate is substantially higher. Some statistics show that in the United States bio cluster the success rate is ten times higher than in the other areas.

58.4 Also we like accepting smaller companies. Smaller companies today could be large investors tomorrow, and smaller companies usually have less commitment to the past and have the freedom to move quickly. In the two areas of biomarker emerging technology and stem cell research, collaboration between the public and private sector is inevitable, and also clinical research collaboration between the government and industry medical institutions is also key.

58.5 I would like to mention one point about parallel trade. We all know it is a lawful transaction; however, our concern is about patient safety because of wrong and missing information on leaflets, and about side effects or dosage in the repackaging process. This could damage people's health and invites some risks of counterfeit products coming in. We know it is all lawful but we have slight concerns about patient safety.

58.6 Let me touch on the Japanese pharmaceutical industry. We are rapidly globalised; although in the European Union we are still small in terms of operations, we spend substantial amounts on clinical research. Investment for discovery areas has started and the production area is also going on. We look at the European Union as a good place to create knowledge together.

58.7 Finally, I would like to touch on the point about patients. Patients are the true customers of healthcare products and services. Both government and industry need more effort to know how our customer is satisfied or not satisfied. What are their priorities?

59. Jane Kennedy (Department of Health, UK):

59.1 Thank you very much for that Mr Naito, and in fact, I was surprised we have got this far in the discussion without parallel trading being mentioned. I am aware of the concerns that there are around the table amongst industry representatives about that particular issue. Are there other people who wish to comment?

60. Mr Thomas Lönngren (European Medicines Agency):

60.1 Since the European Medicines Agency is the gateway for innovation into the European Union I think I should I try to explain a little to you how we are taking this responsibility into the future, especially when it comes to innovation research and development. A year ago we launched what we call the European Medicines Agency Roadmap 2010, which is a long-term plan of how we are taking the European regulatory system and the European Medicines Agency into the future. We had a stakeholder consultation and we had full support in the end from all patients, healthcare professionals, industry, governments, and finally the management board of the European Medicines Agency.

60.2 This Roadmap deals with four issues: first, how we will improve safety of medicines; second, how we will improve access to medicines and also help to improve drug development; third, how we will improve information, communication and transparency, and lastly, how we operate the European regulatory network – European Medicines Agency together with the national agencies.

60.3 Let me concentrate on the issue of what we are doing in order to improve access to medicine, and what we could do from the regulatory point of view in order to improve drug development, and here we have good help from the new pharmaceutical legislation which has now been revised. It came into force a week ago and includes many new tools that will improve access to medicine, and also improve the possibility for us to give advice to the pharmaceutical company when it comes to research and development.

60.4 We have a revised scientific advice procedure. We will give broader scientific advice early in drug development to the pharmaceutical companies. We are setting up a 'Small & Medium Sized Enterprises' office in order to get special support and advice to small and medium-sized companies operating on the European market.

60.5 We have introduced the possibility of getting fast-track approval for new medicines. We have introduced a procedure in order to get conditional approval for medicines. These are incentives in order to get the medicines quicker to the market.

60.6 The issue of how we could help the pharmaceutical industry to improve drug development has been addressed previously here with regard to the European Technology Platform, which is an extremely important European project. I really hope that all the member states will support that when the Council has to decide about allocation of the budget.

60.7 The issue here is to be able to look into the problem of the increasing costs for drug development, and the issue of the failure rates that increase costs of drug development. Here we have identified bottlenecks that in the relative short term could lead to improvement of drug development by firstly stopping some drug candidates earlier before

they cost too much money, and secondly by speeding up the drug development time which is a long time today and time costs money. We are working closely together with all the stakeholders in the technology platform and also with the pharmaceutical industry, and we will give full support to these initiatives.

60.8 We have established a collaboration agreement with the US Food and Drug Administration (FDA). Drug development today is global and there are two big regulators in the world that set the standard for drug development – the FDA, obviously, and now more and more the European Medicines Agency, with the European regulatory network, setting the standard.

60.9 We have initiated a very close collaboration with the US FDA, and we now have the possibility for a company to have parallel scientific advice from the two agencies. If we could come to the same advice we will bring down duplication of research and development costs for the pharmaceutical industry, which is a good initiative to help innovative medicines coming to the market. So this is an example of what we are doing in order to improve research and development in innovation, and that is our contribution to this.

61. Jane Kennedy (Department of Health, UK):

61.1 Thank you Mr Lönngren, that is very encouraging.

62. Dr Alfred Caruana Galizia (Malta):

62.1 Thank you very much Minister for allowing me this opportunity make a few remarks. The national health service in Malta provides healthcare free of charge across the board, and it actually accounts for about 95% of health-related activity, but parallel to it there is a small but significant private sector, which of course responds to the usual parameters of demand, supply, availability and so on.

62.2 Naturally the government decides on what medicines to purchase and from whom and so forth, but in the private sector there is no such restriction and all the new medicines which come on the market, so long as they are imported to Malta, naturally become available on the local market. It is true of course that being a small country with a population of only 400,000 we must account for a very, very tiny fragment of the pharmaceutical market in Europe.

62.3 It is only natural that our government has to be very sensitive to costs and we are indeed rather proud of the fact that we run one of the most cost-effective healthcare systems, which according to the World Health Organization puts us at about number four worldwide. However, this depends on very careful allocation of funds within the healthcare system, and it is only natural, with our obvious restrictions relating to our size and to our industrial

capabilities and so forth, that to a considerable extent the government healthcare system has to rely considerably on the use of generics. This is not to say that it is a kind of easy-going situation where we go for the cheapest. No, we choose our generics carefully, but we tend, on the whole, to go for them for obvious reasons, and these are the reasons of cost.

62.4 Of course we realise that the pharmaceutical industry is most interested in aspects relating to investment in research and development of new drugs and so forth, and this is the way it has to be, but from the point of view of our government naturally our main concern is to do the best we can for our patients to improve the quality of their life, and to be able to respond to their needs as best we can at all times. Thank you very much.

63. Jane Kennedy (Department of Health, UK):

63.1 Thank you very much for that. I have two more people indicating, Andrew Witty from Glaxo, and then Miss Lyngvig from Denmark, and I will keep my eyes open for further contributions.

64. Andrew Witty (GlaxoSmithKline):

64.1 I just really wanted to make a very brief comment with regard to what would make Europe more or less attractive for the location of research and development. I believe we should bear in mind the very rapid emergence of, for example, India, China, Singapore and other newly emerging research and development competitors to Europe. It would be highly ironic and very sad, when these regions were embracing more fully intellectual property protection, which really is a fundamental signal of commitment to innovation, if that was to happen at the same time as Europe was continuing to link for example generic to innovative drug pricing, because while that does not have a direct assault on patents it clearly undermines the value of having a patent.

64.2 There is a real danger for an investment decision maker, particularly one who sits outside of Europe, and where they have a choice of locating within Europe or within America or within Asia, to simply ask the question which of these three regions actually sends the biggest signal of welcoming high-risk innovation through their intellectual property, both through the formalised patent system, but then, more importantly almost, through the way in which that is reinforced in the tactical implementation, for example, of price structure. We have to be very careful that the competitive set for Europe is not stable, and we are seeing an emergence of substantial new competitors for research and development location.

65. Mrs Jytte Lyngvig (Denmark):

65.1 Following what Mr Witty said before about lessening the tensions: in this area, one of the more valuable environments for innovation could also be – and this has not been brought into the discussion before – to take more care of the old products.

65.2 All safety incidents with old products urge politicians and authorities to go for a more risk-aware attitude even if we do not like it. So, I address the industry and say please take care of your old products from a safety point of view as it would be a tremendous help for authorities and governments. This is the way forward if we want to have a fruitful relationship with patients built on trust and confidence.

65.3 At the same time, while we are evaluating, I refer to your contribution, Mr Witty. As mentioned by Finland, the risk/benefit balance moves through time. So, even if products and treatments are evaluated once, we should also remember that new products and treatments progress and other changes should be taken into consideration. I also support what Mr Thomas Lönngren from European Medicines Agency said and others have contributed to.

65.4 The European Technology Platform is a major scene between all stakeholders. Stakeholder relations play an important role not only at the European level but also at the national level. Therefore, we must realise that we have to look both nationally and at a European level in order to make sure that the right risk/benefit assessments will be made. It is important to inform academia and industry that authorities do not only contribute from an economic point of view to future research. Authorities, regulators and pricing authorities should also contribute to research projects with knowledge and experience.

66. Jane Kennedy (Department of Health, UK):

66.1 Thank you for that. I am going to ask Mr Spanniger from Austria now to say a few words. I welcome him and I look forward to hearing his contribution. He will be taking on this role very shortly so it is going to be useful to hear what he thinks.

67. Mr Gernot Spanninger (Austria):

67.1 Madam Chairman and delegates, Austria is grateful for this meeting today because we are provided with a lot of essential knowledge that helps us to form our considerations when Austria takes over the presidency of the European Union. My remit is basically to gather as much information and knowledge in order to then use it for the next six months. However, I would like to mention a few points as well.

67.2 I have been taking part in these discussions for a long time and the G10 recommendations were discussed in Rome, and then implemented in Austria in a reform of our health service. It was not easy, however, because the structures also on the provider side were such that an extension of the generic market, and of the over-the-counter market in connection with industry and medical service providers was such that it was very difficult to get development started in order to get some changes introduced.

67.3 Another challenge was to get products very quickly into the market. In Austria we have a new reimbursement system and that makes it possible that new products, as soon as they have their proper registration, are immediately covered by reimbursement. This system has been running for a year now, but it still has difficulty in being taken up and it needs some time probably for everybody to get used to it. We are discussing here requirements on an international level and those international recommendations take their time being implemented nationally.

67.4 A second point for us in Austria is that we have very intensive contacts on a political level, on a ministerial level, as well as on an expert level with the new members of the European Union. We can assure you that the provider side, the industry in other words, makes its views very clearly known, but that the demand side is very differentiated and very distinct. In some countries a lot of it is concentrated very centrally in their structure, in others it is a more federal system, whilst others have a very high degree of financing, others are publicly financed, and others are financed privately. So, it is very difficult to see a common structure that would possibly apply to all of us.

67.5 Fortunately we have a really important project in co-operation with the WHO looking at the pharmaceutical market in all 25 European Union member states. [For more details about the Pharmaceutical Pricing and Reimbursement Information Project please see the Annex C to this report.] We have the approval for this and on 1 July 2005 the work started on this project, and I assume that all member states are aware that they have experts in this group. Our big hope is that in the six months of our European Union presidency we will be able to present this study, so that at the very least we have a basis for discussion that we can provide which shows us what we are talking about if we talk about requirements which have to be implemented in 25 different ways. That is why I would like to hold back today a little bit and try to find out how far this study has progressed; however, Austria does see cause for presenting its own experience for the new member states of the European Union.

67.6 A second project that has been confirmed in that respect is with the World Bank in New York which is financing a project about the accession countries – Croatia, Bulgaria, Romania. It is a financing a project together with us where we are comparing in a dialogue the health systems and the pharmaceutical systems in those countries that will be acceding

to the European Union, and their systems are being compared in this project with the systems that are in position and in practice in the European Union. So, that is another factor that would make it possible for us to offer something positive and something interesting, and it is something that might be of particular interest for providers and the government representatives alike.

68. Jane Kennedy (Department of Health, UK):

68.1 Mr Spanniger, I wonder whether I could ask you a question. You said that notwithstanding the fact that within Austria you recently decided that reimbursement will allow the medicines to be delivered very quickly, nonetheless there was still some lag in the system. I wonder if you have any thoughts on what those problems are. In the UK my hunch is that partly it is a conservative approach from clinicians, and partly it is that if a new product comes to market halfway through a budget year budgets need to be realigned and that takes a little time to do. I just wondered if there were similar experiences in Austria, or whether there are other factors that perhaps we have not experienced.

69. Mr Gernot Spanninger (Austria):

69.1 One factor cannot be avoided and that is the pharmaceutical market itself is partly budget-driven and has to be looked at from that aspect. It is no secret that the budgets are in a difficult situation in Austria at least in the different segments, and this means that it is not very easy to just introduce new products, and to extend growth and expenses that would go beyond the framework and impact on other areas as well, and we need a fixed budget in this area too. This means that access for innovative products is quickest in hospitals, whereas in the GP framework where the reimbursement is a dominating factor there is an extra element of control for the GPs linked to medical insurance schemes as to whether this medication is really essential for the patient.

69.2 Until prescription is free there has to be a certain peer control by medical professionals in this control of the hospitals, and this change on this control has not actually developed so quickly that it would allow a quicker introduction of medications to the market. We see an extension of it from one quarter to the next, and the dialogue between the companies and the medical profession and the healthcare providers is getting more intensive, so we are hoping that this problem will be resolved in the near future.

70. Jane Kennedy (Department of Health, UK):

70.1 Thank you for that. I felt it was useful just to seek to draw that extra point out. We have not focused particularly on information to patients but we have touched upon it a number of times, so I am not going to invite you to consider that further this afternoon. Before I turn to Mr Zourek to say a few words about the Pharmaceutical Forum I am going to ask Sir Tom McKillop to give us a final reaction to the discussion that we have just heard.

I know Tom is tired of everybody saying it but he is retiring to take up a new job, which is what we are all being invited to do in the UK at the moment. Sir Tom, would you like to say a few words on behalf of the industry?

71. Sir Tom McKillop (AstraZeneca):

71.1 Thank you very much Minister. Yes, in a few days I shall retire from this industry after 36 years. I am a research scientist and I joined this industry because I wanted to be involved in bringing innovative new medicines to help patients. That was my whole purpose and I joined the industry because only the industry is able to do that. There is almost no other source of new innovative medicines for patients other than through the pharmaceutical industry. Let me also say that throughout my whole career I have wanted to see the products that we have discovered and developed available to patients throughout the world at prices that they can afford.

71.2 I have been reflecting on this morning's discussion carefully and I have a few observations to make, and maybe you will allow me a little bit more than two minutes. As you heard earlier, Europe dominated this industry. Europe led the world in innovation in pharmaceuticals and has dramatically lost competitiveness over the last ten to 15 years particularly. That argument seems to be over. The facts are so compelling I hear no one challenging that now. We clearly have lost competitiveness and the question is why.

71.3 If we want to address that loss of competitiveness we really need to understand the reasons. I have been listening to the discussion, which was a very rich discussion, and you can group the reasons into three. First of all Europe's relative research base has been weakening very substantially. The United States government spends five times more of its GDP in healthcare-related research and development, not buying medicines, but in research and development in healthcare, through the National Institute of Health, National Cancer Institute and many other organisations. They spend five times more of their GDP than Europe on average spends. This has led to the United States being the leading edge of biomedical research. Europe has lost its pre-eminence in biomedical research. Things are buzzing in North America and they are not in Europe!

71.4 Now we have Framework Seven and the Innovative Medicines Initiative, and these are opportunities for Europe to get its act together to compete again because there is nothing fundamentally stopping us competing. We have the intellectual talent. We have all it takes, but we just need to get on and do it.

71.5 Also, the loss of our research base is really significant to patients. For instance, clinical trials in Europe have become so expensive that we go elsewhere. Why are they so expensive? Because the industry has been seen as a profit centre for hospitals. We pay outrageous prices to conduct per patient clinical trials in many European centres. This is not the way to

go forward if you want to incentivise clinical research, and as you heard earlier from the Cancer Patient Coalition, patients' access to clinical trials is one of the most effective ways of getting access to the latest innovative technologies, and it can save thousands upon thousands of lives.

71.6 The second reason is market distortions. We do not have a single market in healthcare, and particularly in pharmaceuticals in Europe, we have an extremely fragmented market. It is a mess! There is uneven access and there are delays all over the place, and you heard the frustration of the Director General of the European Medicines Agency that patients are not getting approved medicines, or not getting them for a long time in Europe.

71.7 We have a downward spiralling of prices. As one country arbitrarily overnight imposes a price cut, that becomes the location for a parallel trade industry, and it creates a supply chain that is a total mess. It is completely inefficient, and it is bringing extra risk to patients. We have products moving all over Europe and repackaging of all kinds of crazy things going on. Not only is it a risk because the product quality may be impaired, but we have created a perfect entry point for counterfeiting. We are going to see an enormous increase in counterfeit medicines and this is something that has to be addressed if we are going to deal with patient safety in this area. So we have a compete mess of a marketplace in Europe.

71.8 The third reason, and perhaps the most fundamental, is that for many years now in Europe our focus has been on cost, not on the value of medicines to patients, but also it is has not been on value in terms of a total economic sense. The reason that the Pharmaceutical Industry Competitiveness Task Force was set up in the UK is that for the first time we said "Let's look at this holistically. Let's look at the total cost, the economic value." Europe is the net economic beneficiary of our successful pharmaceutical industry. Indeed the pharmaceutical industry is Europe's most successful high-tech industry even today, and it is dramatically losing competitiveness. We are dramatically losing the economic contribution from this industry to Europe, so the focus must be on value, but not just at patient level; on value in a total economic sense to Europe.

71.9 A word of caution – I heard many references this morning to health technology assessment. Health technology assessment at the time of approval is not your saviour. Almost never in the history of medicine has the first drug in a class been the best drug. Incremental innovation is vitally important. You never know the full properties of a product at the time of approval, and the suggestions you have heard about continuing to review this during the lifetime of products I believe are very important.

71.10 What for me is very clear from today's discussion is that there are serious concerns about the future, and that there are concerns about pharmaceutical innovation in Europe in the

future, but the ministers around the table should be very aware that the concern is not about the future of pharmaceutical companies. The companies have an excellent future. The demographics around the world are fantastic. They are in favour of our industry. There are exciting opportunities emerging in markets all over the world for our industry. The industry will do well going forward.

71.11 The concern you should have today is not about the pharmaceutical companies, it is about Europe. Does Europe really want to have innovation in healthcare or not? I believe that is the central issue that you really have to address, and I would hope today can be somewhat catalytic in moving forward. We have had many, many cycles of discussion. There is a framework laid out in G10; it is now time for action. We really need to implement these things if we want to retain a highly innovative, highly contributing economically industry for Europe. If Europe cannot win in pharmaceuticals, in what industry can it win? I believe that is your challenge going forward and I wish you good luck with it. I hope today will be the beginning of a successful series of meetings about implementation. Thank you.

72. Jane Kennedy (Department of Health, UK):

72.1 Thanks Tom. Can I wish you on behalf of all of the European countries and organisations that you have worked with over the years a long and happy retirement – a busy one I gather – and express our gratitude to you for your commitment to improving and sustaining the health of our peoples, and at the same time improving the wealth of the overall economies that we are here to protect.

72.2 Before I summarise what for me have been the main points coming from today's event, I would like to get an update from the European Commission on how it will take the Pharmaceutical Forum forward. I am going to ask Heinz Zourek, Director General of Enterprise and Industry at the European Commission, to give us the latest news on the development of the Forum, and also to comment on the views expressed during the discussion today and how these might inform the development of the Commission's strategy.

73. Heinz Zourek (European Commission):

73.1 First, I would like to thank you for organising this highly interesting conference in such a splendid environment! It is good preparation for the Forum so I am delighted to be here to address you.

73.2 The two questions that have been discussed today are: why do we need a competitive pharmaceutical industry in the European Union at all, and, if we need one, how could we go about having one? I believe that the 'why' question has been broadly responded to, and it is one that goes beyond the mere pharmaceutical sector because we also have to take into account that it is also contributing to employment in a considerable way, and to

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the employment of highly skilled people. It is an essential foundation of the scientific-based economy which cannot be given up. It is, therefore, also contributing to our science base.

73.3 Having answered the question of why, we should look at how we can achieve this. I must admit that my view is biased by my responsibilities within the Commission and particularly two aspects: the competitiveness of the sector, and the safety and health aspect; not into public health or the financing of health systems. The points that have been raised here are extremely important and have an impact on the competitiveness of our industry.

73.4 What is the Commission's role in this? We mainly have to deal with two things: one, where we are responsible, that is the European legislative framework, and the one we are not responsible at all, the national legal or regulatory environment, but where there might be an impact on our areas of responsibility, and so we created a Forum.

73.5 We are approaching competitiveness from different angles, one of which is our overall policy to improve Community legislation. Better regulation is something that is considered to be essential as a contribution to the competitiveness of Europe. It is part of the Lisbon programme, and it is also determining the views of Vice-President Verheugen who wants to make better regulation his most important contribution to Europe. A key aspect of this policy is to accompany all our proposals with a competitiveness analysis including an impact assessment and also submit it to public consultation so that we can have early external input into it.

73.6 On 20 November 2005, the most recent package of reforms in the pharmaceutical legislation came into force. I do not intend to quote all the elements of it but it was an impressive step in the right direction.

73.7 We also see that if you address a challenge with the right instrument you can make a difference. Orphan medicines have already been mentioned today and this supports the idea that if you get the right instrument with an incentive to do something you can make a difference, and I am proud of the fact that we now have 24 medicines being developed and authorised for rare diseases. This is an achievement.

73.8 I hope, as I see developments in the European Parliament and with Council, we can have, before Christmas, an agreement on medicines for children. This is also very important for us and it is not only essential from the competitiveness point of view, it is certainly everybody's wish that we have the best medical treatment for children that we can provide.

73.9 This is, of course, something that is important and we hope that the third big project that we have put on its way will meet a similar success, which is the innovative treatments that address unmet medical needs; in particular gene therapy, cell therapy and tissue engineering that the Commission has now presented to the Council and to the European Parliament recently. I am steering this process, which will be highly contentious but also important, and I look at it as a big challenge for both the treatment of our patients but also for the industry, and it is in our interests that we do not give too much headway to our competitors when developing these techniques.

73.10 The Pharmaceutical Forum should now address, in particular, those issues which are not covered by Community regulatory approaches. It should cover the 'non-legislative areas' as we call them in our jargon, although they might be legislative at the national level. We are refocusing our needs there. We will also try to respond to what the G10 medicines group has left us: pricing, relative effectiveness and information for patients.

73.11 Now we will try with this high-level Pharmaceutical Forum to be as comprehensive and as open as we can, and this means that we have the Vice-President in charge of competitiveness and the Commissioner in charge of public health and consumer protection together. They will chair it and we have invited all member states, industry and other key stakeholders, including patient representatives, to come and to contribute. We hope that this Forum creates momentum and brings about a broad political mandate for activities that then have to be pursued at the national level.

73.12 We have this Forum, but we want to support the work of the Forum by three working groups which will address the remaining G10 issues of information to patients, pricing and relative effectiveness. We are considering whether the planned EuroPharm database, which is now being developed by the European Medicines Agency, could be complemented by some other information that would then be accessible to patients or to interested people, and whether this would also be suitable as a private/public partnership.

73.13 On relative effectiveness we want to look into how we can support member states and industry growth by finding common accord on how to assess therapeutic value and cost-effectiveness. This would have tremendous potential savings for industry if you only have to produce limited specific national data requirements, and not repeat all the data that is common for everybody.

73.14 Pricing and reimbursement is the most difficult challenge because it is the one that, at the national level, confronts those that are in charge of the health system and its financing, and those that are concerned with public health in general. What we will try to do is to compare, on the basis of an independent study, what alternative approaches are used and what potential solutions could be found to allow industry a more flexible setting of prices without having the consequence that national health budgets would suffer.

73.15 It is quite clear that this is a sensitive issue and that there is no obvious solution because if there were one it would be applied everywhere; however, this initiative could take us forward in this discussion. We should also be clear that some of the measures that are taken at a national level with a short-term perspective might have a very unwanted long-term effect.

73.16 The third element that we try to address, and this has been addressed also here, is innovation, and I must admit that we face a bleak prospect. It would sound optimistic if I say, yes, we have a Seventh Framework Programme, and we even have a competitive innovation programme, and it would be nice if I could say, yes, we will for the years 2007–2013 have some €70 billion to be spent on the support of research and development, which would represent about 10% of the public spending of the Union, and out of this €70 billion about €8 billion should be used for research in health-related projects, but the realistic tone that I want to bring into this concerns two things. One element is that the figures that I quoted were the Commission's proposal as yet unconfirmed.

73.17 The second point is really worrying. I said the Commission's proposal for the period of seven years was €70 billion which brings us to €10 billion a year. But even this amount will do little to fill the research gap between Europe and the USA. The difference between the spending on research and development between the United States and the European Union is around €60 billion p.a. This just shows you the order of magnitude of the problem we are facing.

73.18 In the longer term, Vice-President Verheugen also has agreed with Mrs Kroes, Commissioner for Competition, that there should be a new definition of the code of conduct, or the rules that are applicable for state aid for innovation, and innovative-related expenditures or state aids. We hope that we can do something about this despite the rather modest financing that we can provide to our industry and research institutions.

73.19 An initiative that has been quoted on several occasions already this morning, the joint technology initiative, is important, because this could bring a value-added dimension by having a dialogue amongst those that are in charge of the pre-competitive research.

We want to find a better way to create value-added, by avoiding duplication, and enhancing the effectiveness of the funds devoted to this research.

73.20 I am sorry for having taken so long and postponing your lunch, but I thought that it should be quite clear that we are putting this Forum into a greater context because we think that the Commission should be in charge of the Community regulatory approach, and some considerations on the competitiveness, and that it would be utterly useless to do this only at the Community level and not to have this kind of common deliberation with all concerned stakeholders and member states. We have to stop thinking in the different boxes of being in charge of the health policy, being in charge of the budget, and being in charge of the research and the industry. This is the reason why this idea of the Forum has been brought up, and for the time being it has received a response which is rather encouraging. The discussion we had this morning shows that there is an interest, and there is also a commitment of all the stakeholders to make use of such a Forum. Thank you.

74. Jane Kennedy (Department of Health, UK):

74.1 Thank you very much Heinz for that update on the Pharmaceutical Forum. You have clearly set out for us the process that we all must engage with if we are to achieve our aim of having new medicines for patients developed by a competitive European-based industry. It was very sobering to hear both from Tom earlier and then from you just now the assessment of the task that we face; nonetheless, we must be confident. We have a strong science base and a wealth of talent within the European Union. Provided we take the necessary steps quickly we can improve our competitiveness.

74.2 In closing today's meeting I would like to thank you all for what has been a very interesting discussion. We have covered a lot of ground and there is a lot that we can take from this discussion to help move this agenda forward. One of the overall objectives for today was to begin the process of engaging with the various constituents who hold the key to improving the environment within Europe. Judging by the high level of representation and the quality of the debate here today I believe we can safety say that this has been achieved.

74.3 In the first session this morning we looked at the reasons why we need a competitive pharmaceutical industry in Europe. David Sainsbury set out for you in detail the impact to the economy of losing ground to the United States, and the challenge of the emerging markets of China and Singapore. What struck me most about the position outlined by David was how the number of top ten medicines discovered in Europe fell from six to two within ten years, and while recognising the global nature of the industry, surely it must be in the best interests of the citizens of Europe to have these medicines discovered here, to have the clinical trials carried out here, and brought first to market here.

74.4 In addition to these areas we heard from the patient organisations that highlighted the importance of new medicines to treat life-threatening diseases such as cancer. They also echoed the need for quicker access to medicines – a theme that has run throughout this morning, and I agree that this needs to be addressed, but with patient safety through proper regulation at the forefront of our consideration.

74.5 Member states are facing an ageing population that will have major impacts on our health budgets. New medicines can help, or indeed harness this, and the way forward is through encouraging innovation in the bioscience arena, and Hans Hoogervorst made an important point to us in how we address the brain-drain of our best scientists to the United States. The answer is simple: improve the European environment and by doing that achieve this challenge. But while this is significant in itself, I believe that the main message to take away from our discussion during the first session was that there is plenty of room for improvement.

74.6 The question we then posed ourselves was how we address this space for improvement. I believe that Vice-President Verheugen and Commissioner Kyprianou have provided an important mechanism through their Pharmaceutical Forum. We, in the UK, intend to play our full part in collaborating with all stakeholders in the Forum, and I would like to see all of you there beside us. I believe that if we are to achieve our objective of securing the provision of safe, affordable and effective medicines to our citizens, whilst strengthening the industry within Europe, we need engagement at all levels from the Commission, from member states, from regulators, from patients and from industry. This will provide challenges to all of us and to our constituents, but we need to meet those challenges, and we must rise to the task that faces us. The Forum will provide the underpinning process, but I believe that legislators and policy makers have a role to play by looking at the impact of legislation and policy on industry.

74.7 I am not saying that public health should in any way be compromised, nor do I wish to imply that we should ignore budgetary pressures, but I believe there is room for clearer commitment to proper impact assessment, that when proposals are being developed thought is given to their impact on the competitiveness of the pharmaceutical industry. I am therefore pleased to note in this regard the priority given by the Commission to proportionality in legislation and in regulation.

74.8 In the UK we have been giving some thought to how we engage with the challenges of the future, and ministers and leaders of the UK-based industry meet twice a year. This ministerial industry strategy group is developing a long-term leadership strategy to consider what the environment in the UK might look like in five to ten years in the future. It is in this context that the UK Government will develop the ideas which it will put forward to the Pharmaceutical Forum and its working groups. We have consistently found that

engagement with industry partners has helped both to explain to industry our goals, but also to take on board their ideas at an early stage. I would commend this as an approach to colleagues, and would be interested to hear of their experiences in this regard as we take forward this work.

74.9 Now I must briefly turn to some of the ideas we have talked about today. The first area we considered was pricing and reimbursement, and there are three important realities that have to be recognised here. The first is that there should be appropriate reward for real innovation. The second is that pricing is, and will remain, a national responsibility. We are not talking about motor cars where the consumer very often drives the price and the pricing structure; we are talking about a quite different market. The third point is that we must all recognise and accept that there will always be limits to health budgets, but that said we have had a number of innovative ideas today on how this area could be addressed.

74.10 We had a clear message from Andrew Witty and I believe we all agree with his sentiment that member states have to make choices on how they use their health budgets. Portugal gave a good example of this by the strategic view that it is taking on medicines, and how this reflects the need to incentivise the industry to innovate. Hildren Sundseth from the European Cancer Patient Coalition made the point that agreeing pricing should not hold up access to market, and that agreements on pricing should be made once patients are receiving the medicines.

74.11 Overall there is a general message from industry that it needs stability on the prices it receives to allow it to make decisions on investments for the future. We also looked at how the environment for research could be improved. We know that Europe has historically had a good science base and that our framework for intellectual property rights is second to none; however, we must go forward not back, and again I believe we can take a lot from the discussion. For example, Richard Barker mentioned learning from the United States and developing science-based clusters including universities, secondary care and industry.

74.12 We had a number of interventions highlighting the need to streamline regulation. Mr Lönngren highlighted the work of the European Medicines Agency through its roadmap to encourage research such as providing scientific advice early and introducing fast-track approvals, and a number of member states highlighted a requirement for national health technology assessments. What we in the UK are finding, as a pioneer through the National Institute of Health and Clinical Excellence which I have mentioned a couple of times, is the need to address how patients receive these medicines once they have been assessed, and I am sure that we can share our learning with the Commission. Mr Spanniger set out two pieces of work which Austria is taking forward in this area, and we look forward to seeing the outcome of these during its presidency next year.

74.13 In the past year there have been important developments on public access to data about clinical trials. The World Health Organization is working on standards for trial registration and international agreement on systems to give easy access to the information scattered across registers worldwide. The international industry associations have made constructive public commitments and the International Federation of Pharmaceutical Manufacturers & Associations has launched a new portal for industry trials. The European Medicines Agency is also about to launch a public database, EuroPharm. I am sure that you all welcome these developments as much as I do.

74.14 We then looked at patient safety and the provision of information to patients. We discussed how pharmaco vigilance might be improved and we considered the complex issue of patients being able to get information from the internet without any guarantee of the accuracy or quality of the information that they are receiving. There was a good point made by Dr Schroeder from Germany that Europe does not want to go down the US route of advertising direct to patients, but we do need to provide information that allows patients to make informed decisions.

74.15 The next step from today is that we shall be producing a report of our discussions. This will be passed to the Commission in the hope that it can help inform their thinking for the Pharmaceutical Forum. I will also have copies sent to all member states and to all delegates here today. Richard Pilnik of Lilly and Tom McKillop issued a call to action. We do not normally go from a forum of this nature and issue a call for action, we issue a communiqué or we issue a report, but in concluding, we have heard the message that we have been given from industry today.

74.16 I want to leave you with two thoughts if I may. If we do not begin to address this issue now we will have to answer in the future to our citizens across Europe who will be asking why they are no longer able to benefit from medicines which are developed and trialled here in Europe. They will also be asking us why they can no longer find the high-level scientific careers in medicines development which Europe has had such an outstanding reputation for providing for so long. This is our opportunity to influence the European environment for the innovative pharmaceutical sector. Creating the right conditions for investment and growth is so important, both for our economies and the health of our citizens.

74.17 I would like to thank all of you for working so hard here this morning. I apologise for having to leave you early but I very much appreciate the comments that have been made, the nature of the contributions, the challenge that has been issued to us, and the frankness with which we have been able to engage in this debate. Thank you very much for your time and commitment.

Index of speakers

Jane Kennedy (Department of Health, UK): Para. 1, 3, 5, 7, 10, 12, 14, 21, 23, 29, 32, 34, 35, 37, 41, 43, 45, 49, 51, 53, 55, 57, 59, 61, 63, 66, 68, 70, 72, 74

Lord Sainsbury (Department of Trade and Industry, UK): Para. 2, 33

Dr Richard Barker (The Association of the British Pharmaceutical Industry): Para. 4

Ms Leila Kostiainen (Finland): Para. 6, 52

Ms Hildrun Sundseth (European Cancer Patient Coalition): Para. 8, 48

Mr Anders Olauson (European Patient Forum): Para. 9

Mr John Walsh (British Heart Foundation, Patients Advisory Group): Para. 11

Dr Franz Humer (European Federation of Pharmaceutical Industries and Associations): Para. 13, 36

Hans Hoogervorst (Netherlands): Para. 15, 38

Mr Haruo Naito (Eisai Co., Ltd): Para. 16, 58

Dr Klaus Schroeder (Germany): Para. 17, 54

Professor Salvator Roberto Amendolia (Italy): Para. 18

Mr Ian Read (Pfizer): Para. 19

Mr Per Wold-Olsen (Merck & Co., Inc.): Para. 20

Mrs Jytte Lyngvig (Denmark): Para. 22, 65

Mr Thomas Lönngren (European Medicines Agency): Para. 24, 30, 60

Ms Maria Poncela Garcia (Spain): Para. 25

Mr Arthur Higgins (Bayer HealthCare AG): Para. 26, 50

Mr Dorjan Marusic (Slovenia): Para. 27

Ms Aisling Burnand (BioIndustry Association): Para. 28

Mr Jean-François Dehecq (sanofi-aventis): Para. 31

Mr Hans Christer Olsen (Sweden): Para. 40

Mr Andrew Witty (GlaxoSmithKline): Para. 42, 64

Dr Fernando Bello (Portugal): Para. 44

Mr John Papathanassiou (Greece): Para. 46

Mr Richard Pilnik (Lilly): Para. 56

Dr Alfred Caruana Galizia (Malta): Para. 62

Mr Gernot Spanninger (Austria): Para. 67, 69

Sir Tom McKillop (AstraZeneca): Para. 71

Heinz Zourek (European Commission): Para. 73

Annex A: List of delegates who attended

		Name	Government or Organisation Represented
Mr	Brian	Ager	European Federation of Pharmaceutical Industries and Associations
Prof.	Salvator Roberto	Amendolia	Italy
Dr	Richard	Barker	The Association of the British Pharmaceutical Industry
Dr	Fernando	Bello	Portugal
Ms	Aisling	Burnand	BioIndustry Association
Mr	Emmanuel	Caquot	France
Dr	Alfred	Caruana Galizia	Malta
Mr	Jean-François	Dehecq	sanofi-aventis
Mr	Arthur	Higgins	Bayer HealthCare AG
Mr	Hans	Hoogervorst	The Netherlands
Dr	Franz	Humer	European Federation of Pharmaceutical Industries and Associations
Rt Hon	Jane	Kennedy MP	Department of Health, United Kingdom
Ms	Leila	Kostiainen	Finland
Mr	Thomas	Lönngren	European Medicines Agency
Mrs	Jytte	Lyngvig	Denmark
Mr	Doran	Marusic	Slovenia
Sir	Tom	McKillop	AstraZeneca
Mr	Haruo	Naito	Eisai Co., Ltd
Mr	Anders	Olauson	European Patients Forum
Mr	Hans Christer	Olson	Sweden
Mr	John	Papathanassiou	Greece
Dr	Boleslaw	Piecha	Poland
Mr	Richard	Pilnik	Lilly
Ms	Maria Luisa	Poncela Garcia	Spain
Mrs	Nina	Radeva	Bulgaria
Mr	Ian	Read	Pfizer
Lord	David	Sainsbury	Department of Trade and Industry, United Kingdom
Dr	Klaus Theo	Schroeder	Germany

		Name	Government or Organisation Represented
Mr	Josef	Slany	Slovakia
Mr	Gernot	Spanninger	Austria
Ms	Hildrun	Sundseth	European Cancer Patient Coalition
Mr	Ervin Zoltan	Szekely	Romania
Mr	John	Walsh	British Heart Foundation Patients Group
Mr	Andrew	Witty	GlaxoSmithKline
Mr	Per	Wold-Olsen	Merck & Co. Inc.
Mr	Heinz	Zourek	European Commission

Annex B: Introductory discussion paper for delegates

"Delivering patient-centred innovation in medicines – the role of a competitive European pharmaceutical industry"

Many of the world's leading medicines have been supplied as a direct result of the research and development carried out by the European-based pharmaceutical industry, making an important contribution both to patient-centred innovation and to many member state economies. However, Europe's share of R&D investment by global pharmaceutical companies has declined in recent years, while the US share has grown significantly; and India, China and Singapore are now emerging as attractive new locations for industry investment. This high-level event will bring together European health and economics ministers, leading pharmaceuticals executives and other key stakeholders for a round table meeting. This forum will provide a timely opportunity to consider how the European Commission's newly announced pharmaceutical policy initiative could contribute towards strengthening industry capacity to deliver patient-centred innovation in Europe.

It is proposed that the agenda for this meeting should centre on two questions. The **first** will relate to the economic and social background. The **second** will consider the policies or policy changes that may be necessary if the EU wishes to alter some of the observable trends.

1. Why should the European Union want a competitive pharmaceutical industry?

1.1 **The research-based pharmaceutical industry makes a significant contribution to two of the major objectives of the European Union – improved levels of healthcare for all citizens, and increased EU economic competitiveness on the global stage.**

1.2 A key industry contribution to **improved healthcare** is the development of medical advances. As the source of new medicines for diseases such as cancer, diabetes, heart disease, asthma, and treating mental illness, and of vaccines to protect against infectious diseases, the industry has saved the lives of millions of Europeans and improved the quality of life for many more.

1.3 In this capacity the pharmaceutical industry is generally recognised as a key partner of governments, healthcare administrators, physicians and patients in their mission to achieve better health for the greatest possible number of people.

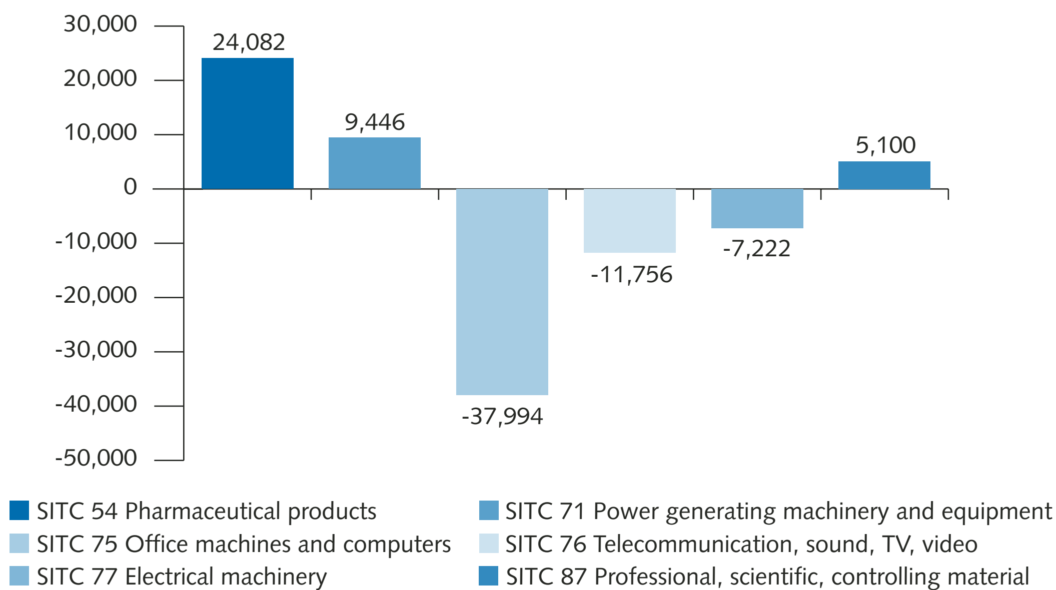
1.4 Achieving better health for European citizens in the future requires investment now. In a speech to the European Federation of Pharmaceutical Industries and Associations in June 2005 Günter Verheugen, Vice-President of the European Commission, said:

> "Europe is facing a huge healthcare challenge...The increasingly elderly population will need ever greater support from hard-pressed healthcare systems. Although the situation is dramatic, we will not succeed in tackling it if we constantly view this as a burden... By investing in healthcare now we can reap rewards in the years to come through reduced hospital care and other long-term support."

1.5 The contribution of the pharmaceutical industry to **economic prosperity and European competitiveness** is also clear. At the primary level the industry employs significant numbers of Europe's most highly educated workers. It is the location of 17% of all EU business R&D, provides over 5% of total EU manufacturing exports, and creates some 3.5% of total EU manufacturing added value.

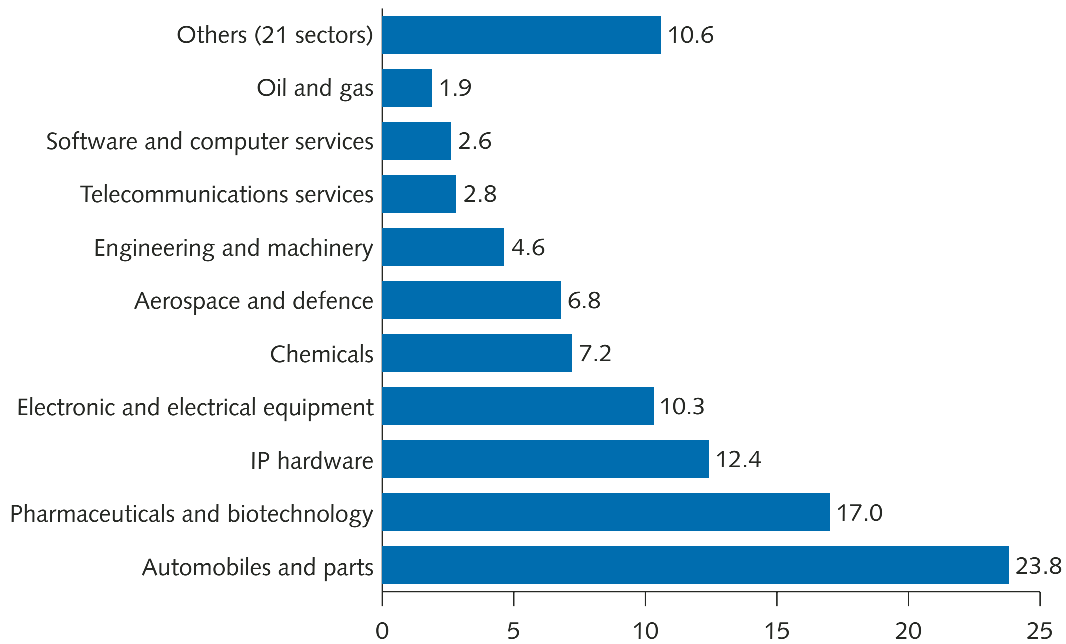
1.6 At the secondary level, the industry creates significant economic multiplier effects, in particular in the higher education sector, contributes to the productivity gains that arise from healthier working populations, and enables economies in public expenditure through healthcare delivery improvement.

EU trade balance of high technology sectors (€ million, 2003)



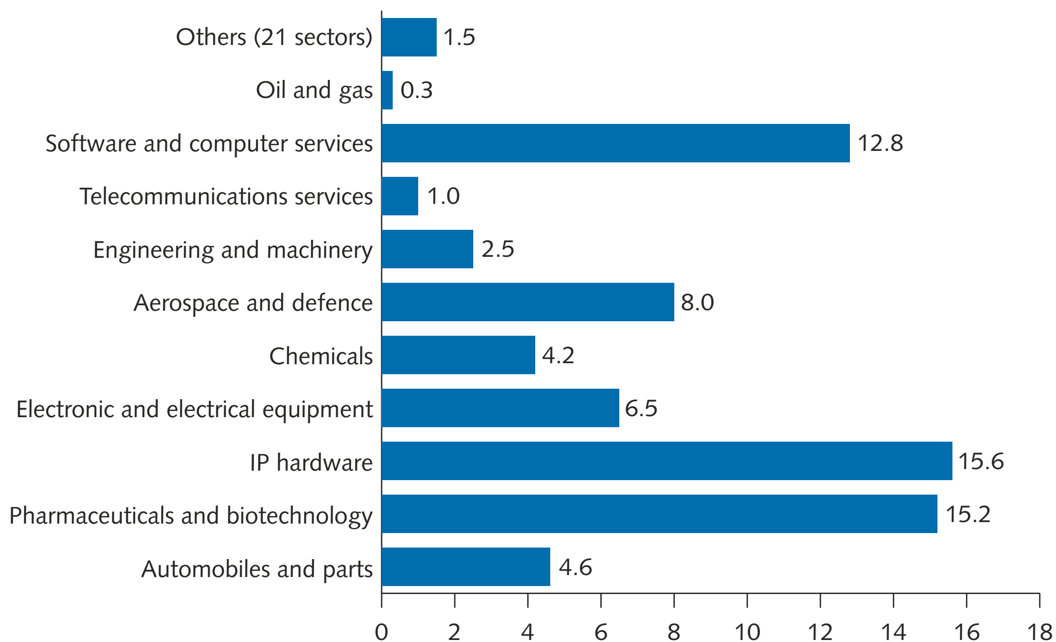
Source: Eurostat

Sector R&D investment as % of all sectors (EU top 500 companies) – 2003



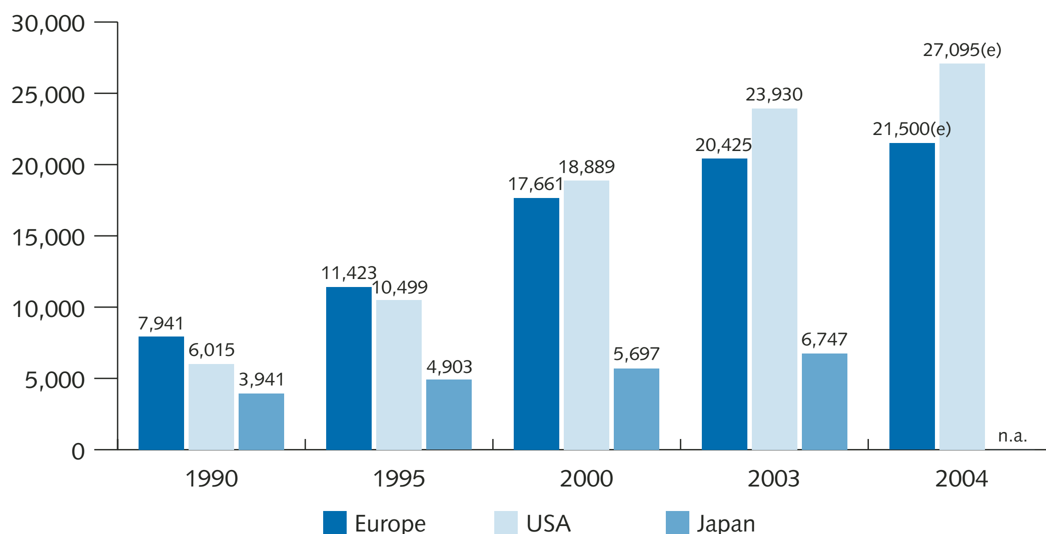
Source: The 2004 EU industrial R&D investment scoreboard, European Commission

R&D/sales ratios for each sector (EU top 500 companies) – 2003



Source: The 2004 EU industrial R&D investment scoreboard, European Commission

Pharmaceutical R&D expenditure in Europe, USA and Japan
(€ million, at 2003 constant exchange rates), 1990–2004



(e): estimate

Source: EFPIA member associations, PhRMA, JPMA

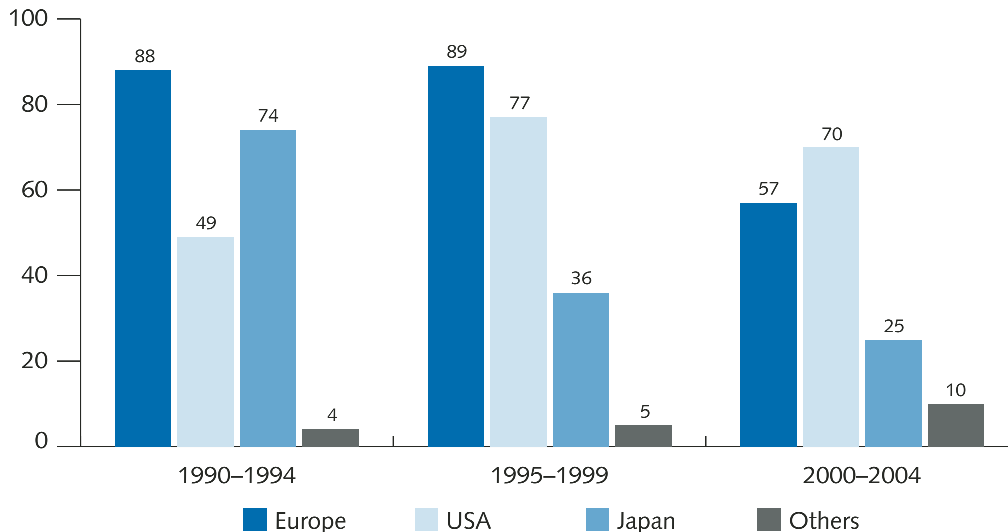
What is the current position with the industry in Europe?

1.7 While these are good reasons why Europe should seek to provide a strong investment base for a globally competitive research-based sector, the trend for investment is not as positive.

1.8 The 2004 European Competitiveness Report pointed out that, despite the positive intent expressed in the Lisbon agenda, there has been little effective follow-through by member states. Business-sector R&D in the EU lags significantly behind its main global competitors, in particular the US and Japan. The report noted that the European pharmaceutical industry, specifically, has become less competitive as an R&D base in comparison to the US. Not only is the EU sector currently losing ground to the USA, but the new contestants of the future are also visible in India, China and Singapore.

1.9 Pharmaceutical R&D investment in Europe, while still growing, has been lagging that in the US for some years. Between 1990 and 2004, R&D investment in the US grew 4.5 times while in Europe it grew 2.7 times. There is currently little expectation that this trend will reverse. The proportion of new drugs originating from the US has now overtaken that from the EU.

New chemical or biological entities (1990–2004)



Source: EFPIA calculations (according to nationality of mother company)

What are the reasons for this?

1.10 The Competitiveness Report outlined some reasons for the deterioration of the policy-environment for research-based pharmaceuticals in Europe, including "the stricter requirements for the testing of pharmaceuticals and the effect of policies to contain health spending".

1.11 Within the EU, pricing and availability of medicines are rightly member state competencies. However, we have seen that unforecastable price changes and availability restrictions can create a lack of incentives for investment. These consequences can stem from a number of factors, such as the budgetary challenges faced by member states, in which expenditure on medicines is routinely an important feature. Access to skilled staff, labour and other costs and taxation rates will normally be important determinants of investment decisions, but other factors, such as the attractiveness of local market conditions and the degree to which national governments are perceived to be committed to innovation, can sway decisions that are finely balanced between alternative locations.

2. How can EU governments and industry work together to provide European patients with innovative and affordable medicines?

2.1 Pharmaceuticals is an unusual sector. Much of the discovery, development and delivery of product comes on a non-contracted basis from the private sector. In the EU, the market is essentially created and funded by governments. The challenge is to identify policy approaches that can deliver all three of: improved EU healthcare; enhanced EU industrial competitiveness; and manageable public expenditures in the area concerned.

2.2 A successful competitiveness agenda for the EU pharmaceutical sector requires an effective alignment of **healthcare** policy and **competitiveness** (or industrial) policy.

The importance of improved national health status is clear: a healthier workforce is a key determinant of sustainable productivity gain. Healthcare expenditure could therefore be considered as an investment and not solely as a cost.

2.3 The commitment made in the Lisbon agenda to move Europe towards a knowledge-based economy provides a good starting point, and the recent announcement by Commissioner Verheugen to advance this through a Pharmaceutical Forum offers a vehicle. Governments and industry therefore have an opportunity to respond together to the challenge of devising a balanced and sustainable policy-environment.

2.4 Perhaps this challenge, which is a broad one, can be tackled through a series of separate questions under the three areas outlined by Commissioner Verheugen of innovation, pricing and benefits to patients.

(i) How can Europe improve its scientific environment for pharmaceutical innovation to regain its competitive advantage?

Pharmaceutical investment (both manufacturing and R&D) is globally flexible to a far greater extent than that of heavy industry. Allocation decisions about new investment can be taken on a truly global canvass, and the industry can serve more markets from fewer locations. Moreover, there is an increasing number of locations that are viable alternatives to Europe – for instance, Singapore, China and India. This factor needs consideration in the design of policy for local or regional investment.

In considering how the environment for innovation might be improved, the delegates might wish to consider some of the following suggestions:

- Framework VII and the Pharmaceutical Technology Platform (*Innovative Medicines Initiative*) recognise that there needs to be a more concerted effort at EU level to encourage co-operation and research in the pharmaceutical field.
- Enhance EU R&D investment through:
  - the growth and availability of appropriately skilled staff.
  - EU funding being directed to develop expertise in biomarker and surrogate technologies and the application of these technologies to drug development.
  - re-assessment of the conditions that can promote the location of clinical research and clinical trials in the EU.
- Improve the interface between public and private research in the EU to reflect the beneficial effects of the Bayh Dole Act and of the National Institutes of Health in the US.
- Develop an EU integrated strategy for biomedical research.

(ii) *How can Europe improve the environment for pharmaceutical innovation by building reward for innovation into pricing and reimbursement systems while protecting healthcare budgets?*

A key to a successful pharmaceutical investment environment is adequate reward and incentivisation of innovation. Against the polarities of strict price control (which squeezes out most incentives) and the call for 'free pricing' (which fails to recognise public-policy realities) it is important to find new pragmatic and effective approaches.

With respect to pricing and reimbursement systems, suppliers of medicines recognise that the days when healthcare agencies were simple price-takers have long since gone. However, alternative systems, which adequately reflect the nature of pharmaceutical innovation and the industry's unusual cost structure, have been harder to agree upon. Various ideas are now in play within the EU, and the search for greater consensus on their relative utility should now be a priority. These ideas include:

- *The development of separate pricing models for separate segments, such as patented, generic and OTC medicines.* Recommendation 6 of the G10 reflected this in its exploration of the idea of removal of pricing controls on non-reimbursed medicines.
- *The improvement of speed of access by patients to new medicines by early un-reimbursed marketing or speedier reimbursement decision-making.* Reconciling this with governments' search for value for money is the persistent difficulty. A better understanding, on the part of both industry and government, of what constitutes added value is required.
- *The application of health economics and of health-technology assessment (HTA).* Both suppliers and purchasers recognise that these technologies do offer assistance, yet they remain contentious. Formal evaluation of medicines is sometimes thought to be used simply to cost-constrain rather than to promote the benefit of the patient. In addition, certainly the use of HTA needs to recognise a number of complexities that surround the nature and definition of a medicine's 'value'.

Therapeutic progress comes in many forms, and while some new medicines may be breakthroughs, others are intended to deliver incremental benefits which are nevertheless of value to individual patients by improving efficacy, tolerability or administration. The data needed to confirm positive health outcomes (or measure value) are typically generated only once a treatment has been widely used, when they may be capable of assessing a product's life-cycle therapeutic contribution. Advances in information technology make it more feasible to take these complexities into account; but it will take time for the necessary degrees of sophistication to be developed, time during which health systems will require assurance that they are not subject to adventitious or exploitative pricing.

Greater agreement on what does constitute value could be served by more structured and systematic dialogue during and after the development of a new medicine.

Whatever ideas are adopted in individual member states, agreement on and adherence to 'the rules of play' can also enhance the climate for innovation.

(iii) *How can the quality of information to patients be improved so that they are more sensitive to the benefits of innovation, more aware of quality-differentials, and more familiar with value in healthcare?*
There is wide acceptance that a key to more effective healthcare delivery is greater patient involvement in, and knowledge of, their conditions and their treatment.

Growing patient involvement will necessitate the development of better and more information for patients on disease, treatments and healthcare options, taking care not to extend to direct to consumer advertising. However, there has to be recognition that patients have access to a vast amount of data through the internet. The meeting might therefore want to consider:

- How we can ensure that best practice is applied across the EU and that all patients have access to the same high-quality information about their medicines – to aim to have all of the EU brought up to the standard of the best.
- How the Public Private Partnership being established by Commissioner Verheugen and Commissioner Kyprianou might improve access to quality information, taking into consideration the accessibility of the internet.
- How current information, such as the Patient Information Leaflets, might be improved.

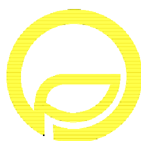
The involvement of patients in the regulatory process is a key development. The question is now being asked about whether, and if so how, the regulatory process might be shortened, but with greater reliance on pharmacovigilance. The delegates may wish to consider how this could be achieved.

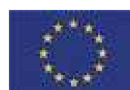
Conclusion

The questions discussed above are complex, and there are no easy answers. The purpose of the discussion on 1 December is not necessarily to identify solutions, but to assist the Commission and member states in the process of finding a way forward that will enable Europe, in the interests of all its citizens, to remain a global centre for the discovery and development of new medicines in the twenty-first century.

14 November 2005

Annex C





ÖBIG WHO – EURO

Pharmaceutical Pricing and Reimbursement Information

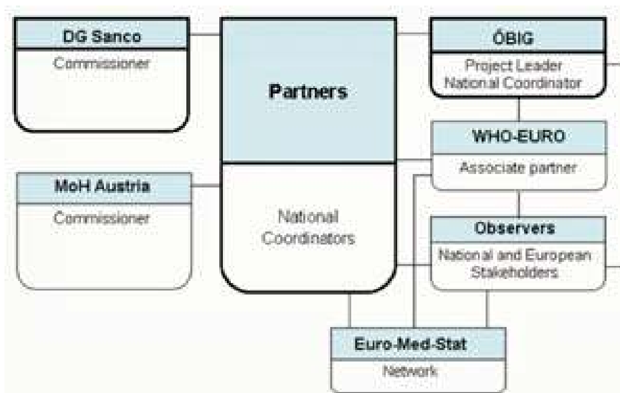
PPRI project

The pricing and reimbursement of pharmaceuticals is a national issue. Consequently there are 25 pharmaceutical pricing and reimbursement systems in the enlarged European Union which often differ greatly. Therefore, the objective of the PPRI project is to develop a network of authorities and institutions in order to improve information and knowledge about the pharmaceutical systems in the enlarged Europe, by providing a comprehensive report with 25 country reports on the Member States and a comparative analysis.

Project organisation

The PPRI project is commissioned and funded by the European Commission, Health and Consumer Protection Directorate-General and co-funded by the Federal Ministry for Health and Women's Issues, Austria. The project team consists of the main partner (ÖBIG / Austrian Health Institute), an associate partner (WHO-EURO) and a network of other partners from a large range of Member States of the enlarged Europe, and Bulgaria.

The PPRI project is designed to run from April 2005 to spring 2007. The results will be disseminated during a **Spring 2007 conference in Vienna**.



Project description

The PPRI project is subdivided into 6 work packages, which are linked to the specific objectives of the study.

Specific objective of the PPRI project:	Work package(s):	Deliverables of the PPRI project:
Strengthening the networking of institutions in the field of pharmaceuticals in Member States	WP 1 'Coordination'	Good communication and cooperation within the project, for delivering a project of high quality on time
	WP 2 'Dissemination'	A website (http://ppri.oebig.at) and a conference at the end of the project (Spring 2007, Vienna)
Assessing the information needs concerning pharmaceutical pricing and reimbursement	WP 3 'Assessment'	A questionnaire to be used in the interviews, with a list of key information and data to be collected
Collection, reporting and analysis of information on pricing and reimbursement in Members States	WP 4 'Survey'	Pharma Profiles (=country reports on the pharmaceutical pricing and reimbursement systems) of the EU Member States
Developing indicators for comparative analysis	WP 5 'Development of comparable indicators'	A list of indicators for analysing pricing and reimbursement in a comparative way
Benchmarking pharmaceutical pricing and reimbursement in the enlarged Europe	WP 6 'Comparative analysis'	Benchmarking of pricing and reimbursement in the Member States in a draft report
Dissemination of project results	WP 2 'Dissemination'	International publications and organisation of the Spring 2007 conference

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"From the patients' perspective it is so self-evident that we must keep innovation in Europe."

Ms Hildrun Sundseth, European Cancer Patient Coalition

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