

PatientView

# **Prescription drug information for the public:**

*A strategy document*

A PATIENTVIEW REPORT

November 2002

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**Interpretations and views in this document are those of PatientView alone. However, every attempt has been made to provide an accurate account of the presentations and discussions that took place at the High-Level Forum held on November 5th 2002 in London.**

## PatientView

PatientView, an independent organisation founded in 2000, provides valuable information about patient attitudes on healthcare delivery and disease-based issues worldwide.

PatientView delivers information in three ways: through specific research reports (whether for general release, or for individual clients); through electronic publishing; and by organising conferences and health forums.

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# Prescription drug information for the public: *a strategy document*

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# Contents

## Letter from the editor

### CHAPTER ONE:

#### **Introduction**

Prescription drug information for the public—an unmet need  
Governments do not want better-informed patients  
The Commission's 2001 proposal  
The UK has taken the lead in advancing the patient's cause  
Involving patients in the NHS  
About the High-Level Forum  
This strategy document

### CHAPTER TWO:

#### **EU initiatives on DTC prescription drug information**

Where patients currently obtain information  
The Commission's proposal  
The debate  
The vote  
What next?  
Questions and answers

### CHAPTER THREE:

#### **Publicly available prescription drug information in the UK**

About IAPO  
About the PatientView and IAPO collaboration  
Why conduct a survey on DTC prescription drug information?  
The survey findings  
Questions and answers

### CHAPTER FOUR:

#### **The Medicines Partnership**

About concordance  
About the Task Force on Medicines Partnership  
From drug compliance to concordance  
An example from the NHS  
Questions and answers

### CHAPTER FIVE

#### **The way forward**

The High-Level Forum meeting  
The rights of patients to information on prescription drugs  
The role of pharmaceutical companies as information providers  
The patient voice  
The way forward  
Conclusion

### List of tables

Table 1.1: List of participants

Table 4.1: Task Force on the Medicines Partnership

### List of figures

Figure 2.1: Sources of information on prescription medicines in Europe

Figure 2.2: The reality for British patients

Figure 2.3: Comparison between nolvadex.com and two British patient websites

Figure 2.4: Contrasting safety information

Figure 2.5: The Commission's response

Figure 2.6: The Commission's proposed amendments to the EU Medicines Advertising Directive

Figure 2.7: Proposed pilot project

Figure 2.8: Rationale for choosing three disease areas

Figure 2.9: Complicating factors

Figure 2.10: Drivers versus blockers of change

Figure 2.11: The European Parliament's response

Figure 2.12: EP plenary vote on October 23rd 2002—Outcome I

Figure 2.13: EP plenary vote on October 23rd 2002—Outcome II

Figure 2.14: EP plenary vote on October 23rd 2002—Outcome III

Figure 2.15: Next steps—Legislation

Figure 2.16: Next steps—Parallel consultations

Figure 2.17: Next steps—Discussion at national level

Figure 2.18: Conclusion

Figure 3.1: Should pharmaceutical companies supply the public with information on prescription medicines?  
The views of UK-based patient groups

Figure 3.2: Why was the survey conducted?

Figure 3.3: Methodology: protocols

Figure 3.4: Percentage of UK patient groups which are either umbrella or patient organisations

Figure 3.5: A few facts about the UK patient groups in this survey

Figure 3.6: UK patients presently get “most” of their prescription drug information from the following sources

Figure 3.7: Sources of prescription drug information most “highly trusted” by UK patients

Figure 3.8: If your organisation were to tell government that more information about prescription medicines should be made available to patients, which of the following would be a priority for you?

Figure 3.9: If pharmaceutical companies were permitted to supply the public with significantly more information about prescription medicines, which of the following forms of communication between the public and the pharmaceutical industry would be acceptable?

Figure 3.10: Would you or your organisation ever approve of direct-to-consumer advertising of prescription drugs within the EU?

Figure 3.11: Should the EU legislate to allow pharmaceutical companies to supply the public with significantly more information about prescription medicines?

Figure 3.12: How should monitoring/policing agency (or agencies) exercise responsibility?

Figure 4.1: Agenda for today

Figure 4.2: Medicines Partnership

Figure 4.3: Non-compliance remains a major issue

Figure 4.4: From compliance to concordance

Figure 4.5: Current policy supports partnerships with patients

Figure 4.6: Levels of patient and public involvement

Figure 4.7: Patient and public involvement—2

Figure 4.8: Patient and public involvement—3

Figure 4.9: “Room for review”

Figure 4.10: User research

Figure 4.11: What patients want from reviews

Figure 4.12: Information needs (1)

Figure 4.13: Information needs (2)

Figure 4.14: Information needs (3)

Figure 4.15: Thoughts about medicines information

## Letter from the editor

In July 2001, the European Commission proposed a pilot scheme to permit pharmaceutical companies to present the public with more information on prescription drugs for three specific disease groups. The Commission's proposal sparked a Europe-wide debate over the topic of direct-to-consumer prescription drug information/advertising (DTCI/DTCA). As part of that debate, PatientView, in collaboration with the International Alliance of Patients' Organizations (IAPO), produced a report, *Should pharmaceutical companies supply the public with more information on prescription drugs? The views of UK-based patient groups*.

Why create a UK-specific report at all? The UK report, launched on November 5th 2002, was born out of a previous PatientView/IAPO EU-wide survey on the role that pharmaceutical companies could play in improving the supply of prescription drug information to the public. The EU-wide survey gave a large number of legitimate patient organisations from across Europe the opportunity to comment on both the benefits and the difficulties associated with the greater promotion of prescription drug information by the pharmaceutical industry. The highest response rates in this EU-wide survey were obtained from the UK. PatientView therefore decided that a UK-specific report was needed to allow further analysis of the opinions of the UK patient group respondents.

The launch of the UK report provided a good opportunity for a further contribution to the subject to be made. PatientView therefore organised, again, in collaboration with IAPO, a High-Level Forum on direct-to-consumer prescription drug information in the UK. The Forum was designed to be attractive to interested parties from virtually every relevant element of the healthcare sector—including even industry representatives. The event was sponsored by Merck Sharp & Dohme Ltd (MSD). To ensure a balanced debate, invitations were extended to both supporters and opponents of DTCI.

The High-Level Forum was held in the neutral territory of *The Economist* Boardroom, on November 5th 2002. Coincidentally, this date was shortly after the October 23rd 2002 European Parliament vote on the European Commission's proposal to amend the Advertising Directive, allowing for "more communication" between pharmaceutical companies and the public on prescription medicines in three disease areas. Although Members of the European Parliament threw out the Commission's proposal, they recognised (perhaps for the first time) that patients do need more balanced information on prescription drugs—particularly new drugs. Thus the PatientView/IAPO High-Level Forum also served to give participants the chance to comment on the European Parliament vote, and discuss possible strategies by which patients could be enlightened about their treatments.

This strategic document is the result of that Forum meeting. Readers will be struck by the extent to which the attending patient groups, in particular, took full advantage of the opportunity extended to them to comment. PatientView has made every attempt to report the events of the Forum in a fair and balanced way. The following pages indicate the main

themes. Suggested plausible action plans are set out. Although much of the debate at the Forum concentrated on the UK situation, these action plans are also relevant to other EU countries. The final chapter should be regarded as PatientView's own interpretation of the conclusions to be drawn from the November 5th 2002 debate.

PatientView would like to extend thanks to: Albert van der Zeijden of the International Alliance of Patients' Organizations (IAPO), for IAPO's considerable input; the UK patient groups attending, whose contributions lent the Forum such significance; the presenters, who gave their permission to reproduce their valuable powerpoint presentations in this document; the sponsor, Merck Sharp and Dohme Ltd, for funding the Forum proceedings; *The Economist*, for permitting the meeting to take place in the magnificent surroundings of its Boardroom; and to all the participants of the High-Level Forum, for showing, by their presence, that they recognise the importance of the patient voice when taking healthcare policy decisions.

Dr Alexandra Wyke  
Managing director  
PatientView  
November 2002

## Chapter 1

# Introduction

*Patients the world over are wanting more choice and say in their healthcare. EU patients, however, have been kept largely in a state of ignorance about the decisions that underlie the care they receive. Theoretically, the situation in the UK should be better than that in the rest of the EU. The present UK government had explicitly used its NHS Plan of July 2000 to state that patients should be placed at the heart of health reform. Since that date, and despite the passage of much rhetoric and legislation, not much has changed as far as the UK public is concerned. The PatientView/IAPO High-Level Forum provides a valuable platform from which to start the debate on possible future strategies to improve the provision of patient information on prescription drugs.*

## **Prescription drug information for the public—an unmet need**

Patients in the 15 member states of the European Union are afforded little choice about their treatments. They do not participate in a meaningful way within their healthcare systems. One reason why EU patients lack a voice is that they have, to a large extent in the past, been willing to relegate the responsibility of their care to doctors. Today, a combination of growing inequities in access to care, declining standards, increased rationing of healthcare services, and a lack of emphasis on preventive medicine have all combined to persuade patients that they need to be more active if their national healthcare systems are to improve.

## **The importance of prescription drug information to patients and the public**

The public availability of useful and high-quality prescription drug information will be a key requirement in the move towards more patient-friendly healthcare systems. Armed with the right information, patients are able to engage in a dialogue with their doctors. Publicly-available prescription drug information can help ensure that patients get the best possible care.

Currently, the vested interests of many of the suppliers of prescription drug information are standing in the way of the dissemination of neutral prescription drug information to the public. Even governments are far from independent on this matter. Pressure on national healthcare budgets has led to the rationing of treatments and to the promotion of the most cost-effective, rather than the best, prescription drugs. Patients have reacted by increasingly distrusting some of the treatment decisions made on their behalf by doctors. PatientView's EU-wide survey found as much, and concluded that patients suspect doctors of sometimes prescribing only the cheaper of the treatments available. More and more, therefore, patients are turning to alternative sources of information to obtain a truer picture of their treatment options.

## **Governments do not want informed patients**

Traditionally, most governments in Europe have (at least in part) managed their healthcare expenditures by regulating patient demand. Minimising patient demand can be

achieved through the control of publicly-available prescription drug information. Portugal, for instance, has possibly the most severe censorship laws regarding public-domain information about prescription medicines. In Portugal, not even the media are allowed to refer to a pharmaceutical product by its brand name.

Although spending on medicines cannot be wholly equated with censorship, differing levels of pharmaceutical expenditure per capita do indeed occur among the 15 EU member states. Patients in Belgium, for example, are allowed more freedom to ‘shop around’ for doctors than patients in virtually any other EU country. Tellingly, Belgium spends over a third more on pharmaceuticals per capita (in dollar terms) than the UK. The Netherlands spends even less than the UK—only 57% of the amount spent by Belgium on pharmaceuticals per capita (in dollar terms).

### **Why prescription drug information is important**

The issue of access to prescription drug information is important. Large numbers of Europeans suffering from serious diseases such as diabetes, HIV, or asthma remain untreated at present. If information about effective treatments were supplied to the public, greater numbers of passive patients would become active in attempting to obtain the treatment they require.

Based on the European Convention of Human Rights, in December 2000, Article 11 of the EU Charter proclaimed at Nice acknowledged that every citizen needs, and is entitled to have, timely and accurate information without interference from public authority. Yet public authorities often determine that patients in Europe are typically prescribed only cost-effective, not the best available, medicines—and patients remain ignorant of that fact. Virtually alone among governmental-level organisations, the European Commission has recognised the legitimate needs of patients to possess more information about their medicinal products.

### **The Commission’s July 2001 proposal**

On July 18th 2001, the European Commission proposed a relaxation to EU rules that prohibit pharmaceutical companies from promoting the use of prescription drugs [<http://pharmacos.eudra.org/F2/review/index.htm>]. The proposed changes, relating to Articles 86 to 100 of Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, were transmitted to the European Parliament and Council in November 2001. The changes to the directive also formed part of a series of proposals regarding EU rules on the regulation of prescription and over-the-counter medicines.

The specific recommendations of the Commission included a relaxation of rules on pharmaceutical information for a trial period, during which companies would be allowed to communicate to the public more information about prescription medicines approved for the treatment of three serious diseases: HIV/AIDS, asthma and diabetes. The three diseases were chosen because treating them necessitated long-term usage of medicines by patients. Information about treatments within these three disease areas would be accessed by individual patients and patient groups, on request, via websites.

The Commission indicated that the European Medicines Evaluation Agency (EMEA), which regulates the approval of EU-based prescription drugs, would be appointed to police the pharmaceutical industry’s publicly-available information on prescription drugs.

### **Factors driving the Commission's proposal**

The main justification given by the Commission for its proposal to relax rules on prescription drug information is the disparity in information on prescription drug treatments that currently exists between US and European Internet sites. Communication between drug companies and patients on the subject of prescription drugs is strictly prohibited within the EU at present. However, no such restrictions apply in the US to US-based websites. The Internet allows European consumers to access information and advertising put out for American audiences by pharmaceutical companies. The Commission has argued that modern information technology has made nonsense of the present ban on pharmaceutical companies supplying the EU public with prescription drug information.

According to the Commission, about 18% of all European households were linked to the Internet by March 2000. This percentage rose to 38% by December 2001. In November 2001, almost 50% of the EU population over 15 years of age used the Internet—either at home, at work, at school, in places of public access, or on the move. So many Europeans accessing the Internet means that a clear need exists to iron out the differences in the availability of prescription drug information between the US and the EU.

The Commission is also concerned to prevent Europeans lacking Internet access or English-language skills from being disadvantaged.

Another factor persuading the Commission to change past policy towards prescription drug information is the steady, unfavourable shift in pharmaceutical R&D investment away from Europe to the US. The US pharmaceutical market has been growing rapidly over the past few years—unlike its European counterpart.

### **The ensuing debate**

On October 23rd 2002, the European Parliament voted on the European Commission's proposals to reform European legislation on pharmaceutical products (European Commission press release IP/02/PHARMA VOTE-EN). Among these proposals was an amendment to the Advertising Directive, which would allow for more "communication" from pharmaceutical companies about prescription medicines in three disease areas. Before becoming law, any such proposal has to be reviewed and adopted by the Parliament and the member states (who have equal say in this legislation). The patient information section, in particular, was hotly debated by Members of the European Parliament (MEPs) before the plenary vote took place. Much of the discussions centred around two concerns: firstly, the fear that the proposal was a slippery slope to US-style direct-to-consumer advertising; and secondly, whether it was possible or productive to differentiate between prescription drug information and prescription drug advertising. MEPs also noted the implied discriminatory nature of the proposed three-disease pilot, with some insisting that the pilot should be extended to all diseases.

Several weeks before the vote, on October 2nd 2002, a number of amendments had been adopted by the European Parliament's Environment Committee (a body responsible for the preparatory work needed before the vote by the full assembly). These October 2nd amendments would have represented a significant step backwards, in that they called for the restriction of almost all types of communication on prescription medicines between the pharmaceutical industry and the public.

In the weeks leading up to October 23rd 2002, some patient groups mounted a concerted campaign to undermine the October 2nd amendments. Groups wrote protest letters to MEPs, complaining that the amendments would diminish, rather than enhance, their access to product information. The campaign resulted in a sea change in thinking by MEPs. Amendments defeated at the Committee stage were re-introduced. These latter amendments made a number of important statements, including: the pilot study should embrace a wide range of diseases (unless there was a threat to health); the pharmaceutical industry should be able to self-police information put out on the corporate websites of its own members; and any drug company literature which simply made patients aware of the availability of medicines would be classified as information, not as advertising.

On October 23rd 2002, the European Parliament rejected the Commission's proposal for a three-disease pilot study. But MEPs also recognised that *"patients have a legitimate need and right for information about medicinal products, including about prescription medicines"*. They also realised that the availability of such information was insufficient, and called for the Commission to begin *"consultations with patient organisations and other interested parties, and present a report outlining a comprehensive consumer/patient information strategy to ensure good quality, objective, reliable and non-promotional information on medicinal products and other treatments."* Based on its findings, the Commission is to propose any legislative changes necessary to enhance the quality of direct-to-consumer patient information on prescription drugs.

Another crucial development occurring during the October 23rd vote is that the European Parliament clarified the definitions of advertising versus information. In the process, the Parliament rejected the amendments of October 2nd, which would have prohibited the pharmaceutical industry from having any communication with the public or patient groups on prescription medicines. Parliament also deleted the phrase *"awareness of the availability of medicines"* from the definition of advertising.

Under the amendments adopted by the Parliament, prescription drug information is defined as follows:

*"Information on 'medicinal products' shall include objective reports on the composition, action, quality, indication, contra-indication and adverse reactions as well as the results of marketing."*

Further explanations on information were provided as follows:

*"The provision of reliable comparative information on diseases, therapeutic strategies and medicinal products is authorised in the interest of patients in order to respond to their legitimate needs."*

Advertising is defined as follows:

*"Advertising of medicinal products shall include any door-to-door marketing, canvassing activity or inducement designed to promote the prescription, supply, sale, or consumption of medicinal products."*

Commissioner Liikanen, though disappointed at the rejection of the pilot study, was encouraged by the call for a more comprehensive strategy for patient information. He responded to the vote by issuing the following statement: *"Swift action is necessary to*

*ensure that patients have access to innovative medicines and to high-quality information on these products.”*

Health Action International (HAI), which argued for the status quo, also produced a press release, declaring a victory in its campaign. This was despite the fact that HAI had argued for the impossibility of distinguishing between the provision of information and advertising.

The pharmaceutical industry has welcomed the European Parliament decision, on the basis that it presents an opportunity for patient groups and other stakeholders to have their voices heard on this vital subject.

Following the vote, Commission officials have indicated that the Commission intends to pursue its pilot project in a modified form—despite the pilot project’s rejection by the European Parliament. The 15 member states, sitting in the Council of Ministers, will now be required to provide their views. As both the Parliament and the Council are co-legislators, the latter has to take the Parliament’s decision into consideration. The Council of Ministers is expected to make its decision in the first half of 2003. If the co-legislators do not agree, the package could go to a lengthy conciliation procedure, which in turn might threaten the Commission’s aim to have the whole pharmaceutical package adopted before enlargement scheduled for 2004.

PatientView is planning a series of further reports in this area.

### **The UK has taken the lead in advancing the patient’s cause**

Since coming to power in May 1997, the Labour government has spearheaded initiatives designed to involve patients in the National Health Service (NHS) agenda. The NHS Plan of July 2000 was the first instance—probably in any country—of patients being placed at the heart of a process of healthcare reform. The framework and principles by which a new patient-oriented culture would be created at every level of the NHS was outlined in the government document, *“Shifting the Balance of Power: Securing the Service”*, published in July 2001. The programme of re-orienting the NHS towards patients was aimed at the level of local Trusts (organisations charged with the responsibility for managing NHS care). In April 2002, *The Wanless Report* recommended big increases in NHS expenditures in areas that help meet patients’ current expectations.

### **New administrative bodies**

In September 2001, the government published a document entitled *Involving Patients and the Public in Healthcare: A Discussion Document*. The document summarised the NHS Plan’s proposals to create a patient-centred healthcare system. Included was an outline of the administrative and statutory bodies that were to be formed to support the government programme *Shifting the Balance of Power of the NHS*. These new organisations include:

#### **Voice**

A statutory body intended to encourage *“public bodies and voluntary organisations and other private bodies to seek views of local communities on health-related issues”*. Voice was first established in September 2001. The then health minister, Hazel Blears, said: *“The patient must be at the centre of everything the NHS does. We want to move away from an outdated system towards a new*

*model, where the voices of patients, their carers and the public are heard at every level of the service, acting as a powerful lever for change and improvement in the NHS.”*

### **PALS**

From April 2002, all Trusts running hospitals, GP practices or frontline community health services have to have put in place a patient advice and liaison service (PALS). According to the NHS website ([http://www.nhs.uk/patientsvoice/at\\_hospital.asp](http://www.nhs.uk/patientsvoice/at_hospital.asp)): *“Patients, their families and carers can turn to PALS whenever they have a problem to resolve, or wish to air concerns about the treatment, care or support they are receiving. Rather than just helping patients to complain after the event has occurred, PALS have direct access to the Trust's chief executive and the power to negotiate an immediate solution. PALS will also feed patients' complaints back into the system to ensure that the right lessons are learned and steps taken to ensure problems are tackled.”*

### **Patient Forums**

Patient Forums are due to be set up by early 2003 in every NHS Trust. Made up of local people, the main role of the forums will be to provide input from patients on the running of local NHS services (and how these services could be improved). Each Patient Forum will have a representative on the Trust board.

### **The Commission for Public and Patient Involvement in Health**

A new commission for patient and public involvement in healthcare will be established in 2003. The commission is to set national standards for Patient Forums. It will also ensure that local people, by working with PALS, get a say in the running of their local healthcare services.

## **Involving patients in the NHS**

As part of the July 2000 NHS Plan, local patient opinions are to be sought, evaluated, understood and acted upon. Trusts will be required to collate patient feedback on the healthcare services they deliver. This feedback has several purposes:

- Improving the standards of local health services;
- Setting benchmarks to track (and hopefully improve) patient experience over time, offering an indicator to the performance of healthcare providers;
- Producing information that promotes greater accountability of NHS healthcare providers to the public and to Parliament.

The government is to begin its schedule of patient assessments in 2003. Once local patient survey data becomes available, Trusts are to ensure that the information is conveyed to all the bodies charged with representing patient interests. Every NHS organisation will have to publish an annual patient prospectus, giving an account of the views received from patients and detailing actions performed in response.

Aside from the above agenda, a separate initiative called the Medicines Partnership aims to take the patient dialogue a step further [see Chapter 4 in this document]. The Medicines Partnership aims to include the patient in decisions about prescribing medication.

## **A potted history of the NHS under Labour**

### **The promise**

When the Labour Party was elected in May 1997, the new government pledged to make radical improvements to public health services. This was to be achieved through major reforms, involving increased state and private-sector investment, and the reorganising of healthcare systems to suit patients' needs.

Labour's National Health Service (NHS) Plan, published in July 2000, set ambitious goals to build new hospitals, hire new doctors and improve the management of secondary care (which was failing to deliver). In addition, all healthcare services were to be made more accountable. New systems were to be introduced that would grade health services on their clinical performance. Last, but perhaps most important, the Labour government set out, in the NHS Plan, a series of long-term strategic aims focusing on the involvement of patients in choices and decision-making within the NHS. By involving patients, Labour believed, the public perception of healthcare could only improve. This was the first occasion in which any government had specifically included patients at the centre of their health reforms.

Other targets were also set. Waiting times for operations were to be slashed. Instead of waiting three months for an out-patient's appointment, for instance, patients would have to wait no more than six weeks. Around 7,500 extra consultants, 2,000 extra general practitioners (GPs), 20,000 extra nurses, and 6,500 extra therapists were to be recruited to make up for the vast shortfall in human resources that was contributing to inefficiency within the NHS.

What has been achieved since the NHS Plan was published?

### **The delivery**

In July 2002, the NHS Chief Executive, Nigel Crisp, stated that the balance of power in the NHS had shifted closer to patients. In his opinion, patients are now being afforded more choice. Certainly, a number of changes have been successfully implemented. For instance, the rating systems for hospitals has been established. And significant funds have been allocated to the NHS to ensure that the quality of care has improved. When the Chancellor announced Labour's Budget for fiscal 2002, included was the most ambitious round of spending ever seen in the NHS. Spending on the NHS is set to grow 7.4% annually in real terms by 2007/08, to bring the UK up to European levels of spending.

Other highlights since 2000 have included:

- The reorganisation of the primary care sector into autonomous Primary Care Trusts (PCTs), controlling 75% of the NHS budget. The hope is that PCTs should be better able to co-ordinate the healthcare needs of patients.
- The nationwide launch of NHS Direct, a telephone service that puts the public directly in touch with medical professionals.
- The setting up across the country of NHS walk-in clinics, allowing patients to walk in off the street and be seen by a nurse.
- The formation of National Service Frameworks (NSFs) for diabetes, heart disease, mental illness and for older people. The NSFs are considered to be high-priority areas

within the NHS. As such, they attract extra funding.

- The formation in 1999 of the National Institute for Clinical Excellence (NICE) to act as an advisor to the government on whether or not new technologies, drugs and treatments should be available on the NHS. NICE, which consists of senior doctors, managers and academics, analyses clinical and cost effectiveness, and also defines minimum universal standards of NHS care.
- The implementation of community care strategies to keep people out of hospital.

### **The general feedback**

Some hospital waiting times for operations have clearly been reduced. Cancer services, too, have vastly improved. More rapid-access specialist and primary care clinics exist. But significant problems remain.

The primary care sector is still weighed down by the bureaucracy involved in the establishment of PCTs. A number of PCTs have overspent budget. The NHS has been unable to attract many of the new staff it needs. During the past five years, the reported incidence of medical errors has increased, as has medical litigation. Large numbers of older people living alone still have difficulty obtaining the resources they need just to stay healthy. People with long-term illnesses are often returned home, even when they probably need hospital care. And, perhaps worst of all, huge inequities in healthcare persist. From the government's perspective, the task remains gargantuan. Yet despite the wide-ranging agenda of the NHS Reform Plan, and its undoubted successes, a new and worrying difficulty is emerging. The public, rather than embracing their new healthcare system, is coming to believe that the NHS may be cutting corners and denying patients the best possible treatment.

### **Consider the problems of getting treatment**

The amount spent on healthcare by the UK government still falls well below that of other countries within the EU. UK spending on pharmaceuticals is just 58% of French levels and 75% of the amount spent in Germany. NICE's increased role in the UK is part of the explanation. During the past few years, the agency has refused to include a number of drugs on the NHS reimbursement list, a policy which has been attacked by patient groups.

Some of the most fraught and bitter battles between patient groups and NICE have been over beta interferon and glatiramer acetate, two multiple sclerosis (MS) drugs that modify the progress of the disease. In August 2000, NICE ruled that these two MS drugs should not be available on the NHS. NICE argued that money which might be spent on beta interferon (around £10,000 a year for each patient) would be better directed at other forms of treatment for MS, such as physiotherapy. The Multiple Sclerosis Society appealed against the NICE ruling. Since then, a truce has been arranged. A UK-wide scheme was launched to prescribe these MS drugs and assess their long-term effectiveness. If the drugs fail to live up to expectations, the NHS will then pay less for them. However, by February 2002, only 2-3% of the MS population were being prescribed these particular drugs, compared with 13-15% of the MS patients in most other European countries.

The practice of postcode prescribing has also been widely criticised throughout the UK.

Postcode prescribing means that patients in one part of the country may not get access to the same range of medicines as patients in other UK areas, simply because their local healthcare payer lacks the budget to afford certain drugs. Many patients now feel that the level of treatment and care they receive from the NHS is largely dependant on the area where they live—which stands counter to the NHS ethos of universal care. Thus irrespective of the reforms Labour has introduced and will introduce in the future, patients who have to interact with the NHS are becoming more dissatisfied.

## **About the High-Level Forum**

Given its slightly more forward position on patient-focused healthcare, the UK is a valuable starting point from which to commence discussions on how prescription drug information to patients might be improved—as recommended by the European Parliament. Therefore, on November 5th 2002, PatientView, in collaboration with IAPO, arranged a High-Level Forum on the subject at the Boardroom of *The Economist*, in London. Attending the Forum were over 40 representatives from across the healthcare sector [see Table 1.1]. The programme for the event was as follows:

### **PROGRAMME**

#### **Welcome to *The Economist***

Clive Crook, *Deputy Editor of The Economist*

#### **Start of meeting**

**Chair:** Paul Wallace, *UK Economy, Pensions and Health Correspondent, The Economist*

#### **Presentation on the EU initiatives on DTC prescription drug information**

Kathy Redmond, *Member, Scientific Committee, European School of Oncology, and past President, European Oncology Nursing Society*

- The Commission proposals
- The debate
- The vote
- What next?

Questions and discussions

#### **Presentation on the PatientView/IAPO survey**

Albert van der Zeijden, *Chairman, The International Alliance of Patients' Organizations, and Vice-Chairman, The Council of the Chronically Ill and the Handicapped in the Netherlands*

- About IAPO
- About the PatientView and IAPO collaboration
- Why conduct a survey on direct-to-consumer prescription drug information?
- The importance of the findings

#### **Presentation on the quality and access to prescription drug information in the UK**

Dr Alexandra Wyke, *Managing Director, PatientView*

- Findings of the PatientView/IAPO UK-based survey of patient groups

Questions and discussions

### **Presentation on the Medicines Partnership**

Joanne Shaw, *Director, Medicines Partnership*

- About the Task Force on Medicines Partnership
- About drug compliance
- From compliance to concordance
- Greater access to prescription drug information

Questions and discussions

### **Panel discussion on future strategies to improve the supply of prescription drug information to the public: future strategies**

**Chair:** Stephen McMahon, *Chief Executive, The Irish Patients' Association and Member, Expert Advisory Group on Media and Health, The Council of Europe*

**Panel members:** Rod Mitchell, *Honorary Treasurer, The International Alliance of Patients' Organizations, and Chairman, The European Federation of Crohn's and Ulcerative Colitis Associations*

and Dr Alexandra Wyke, *Managing Director, PatientView*

### **This strategy document**

This strategy document summarises the findings of the above Forum. PatientView has also attempted to draw out some of the meeting's more interesting themes and suggestions, particularly when they are relevant to the Commission and EU member states. Thus:

**Chapter 2** contains a summary of Kathy Redmond's analysis of the DTIC debate within the EU.

**Chapter 3** describes the presentations of Albert van der Zeijden and Alexandra Wyke. These talks were about the views of a significant number of UK patient groups on the current state of publicly-available prescription drug information.

**Chapter 4** contains an outline of the structure and goals of the UK's Medicines Partnership, based on a presentation made by Joanne Shaw.

**Chapter 5** reviews the main elements of the High-Level Forum meeting and highlights lessons learned from the discussions that took place during the Forum. Listed finally are strategies that have the potential to improve the supply of prescription drug information to the public, together with their possible relevance to countries in the rest of the EU.

**Table 1.1 List of participants**

Andy Burnham MP; Member, Health Select Committee; <b>House of Commons</b>
Margaret Cone; Editor; <i>Regulatory Affairs Journal</i>
Baroness Cumberlege MP; <b>House of Lords</b>
Clive Crook; Deputy Editor of <i>The Economist</i>
John Davis; Editor; <i>Scrip</i>
Martin Dockrell; Head, Policy and Information; <b>National Asthma Campaign</b>
Annette Dumas; External Affairs; <b>Merck Sharp &amp; Dohme</b>
Hugh Ferrier; Head; Account Management; <b>Torre Lazur McCann Healthcare</b>
Christina Funnell; Co-ordinator; <b>Patient Information Forum</b>
Catherine Gooderham; Senior Editor; <b>PatientView</b>
Kevin Guinness; Head, Pharmacy and Prescription Branch; <b>Department of Health</b>
Professor David Haslam; Chairman of Council; <b>Royal College of General Practitioners</b>
Carina Kamel; External Affairs; <b>Merck Sharp &amp; Dohme Ltd</b>
Kieran Kettleton; Director, Communications; <b>Arthritis Care</b>
Jocelyn Luxon; Honorary Secretary; <b>Fellowship of Depressives Anonymous</b>
Baroness Masham MP; <b>House of Lords</b>
Nick May; President, Europe; <b>Ogilvy Public Relations Worldwide</b>
Andrew McConaghie; News Editor; <i>Pharmafocus</i>
Stephen McMahon; Chairman, <b>Irish Patients' Association</b> ; and Member, Expert Advisory Group on Media and Health; <b>The Council of Europe</b>
Rod Mitchell; Honorary Treasurer; <b>International Alliance of Patients' Organizations</b> ; and Chairman; <b>The European Federation of Crohn's and Ulcerative Colitis Associations</b>
Karen Moyses; Managing Director; <b>Kinetic Consumer Communications</b>
Clive Nead; Editorial Director; <b>PatientView</b>
Kathy Redmond; Member, Scientific Committee; <b>European School of Oncology</b> ; and past President; <b>European Oncology Nursing School</b>
Tom Sackville; Chief Executive; <b>International Federation of Health Plans</b>
Joanne Sawicki; Founder and former Chief Executive; <b>Channel Health TV</b>
Joanne Shaw; Director; <b>Medicines Partnership</b>
Marie Taylor; Associate, 'Informed Patient' project; <b>Judge Institute of Management, Cambridge</b>
Kate Tillett; Director, External Affairs; <b>Merck Sharp &amp; Dohme Ltd</b>
Bridget Turner; Head of Policy; <b>Diabetes UK</b>
Paul Wallace; UK Economy, Pensions and Health Correspondent; <i>The Economist</i>
Sian Wilson; Political and Health Policy Manager; <b>Merck Sharp &amp; Dohme Ltd</b>
Lynn Faulds Wood; <b>advocate on behalf of cancer patients</b>
Alexandra Wyke; Managing Director; <b>PatientView</b>
Albert van der Zeijden; Chairman, <b>International Alliance of Patients' Organizations</b> ; and Vice-Chairman; <b>The Council of the Chronically Ill and the Handicapped in the Netherlands</b>

## Chapter 2

# EU initiatives on DTC prescription drug information

*Kathy Redmond of the European School of Oncology outlined the events that followed the European Commission's July 2001 proposal to permit direct-to-consumer prescription drug information (DTCI) in a three-disease pilot study. She discussed both the debate that followed the proposal, and the final vote in the European Parliament on October 23rd 2002. Ms Redmond looked at the Commission's next steps in this area.*

### **Kathy Redmond**

**Member, Scientific Committee, European School of Oncology,  
and past President, European Oncology Nursing Society**

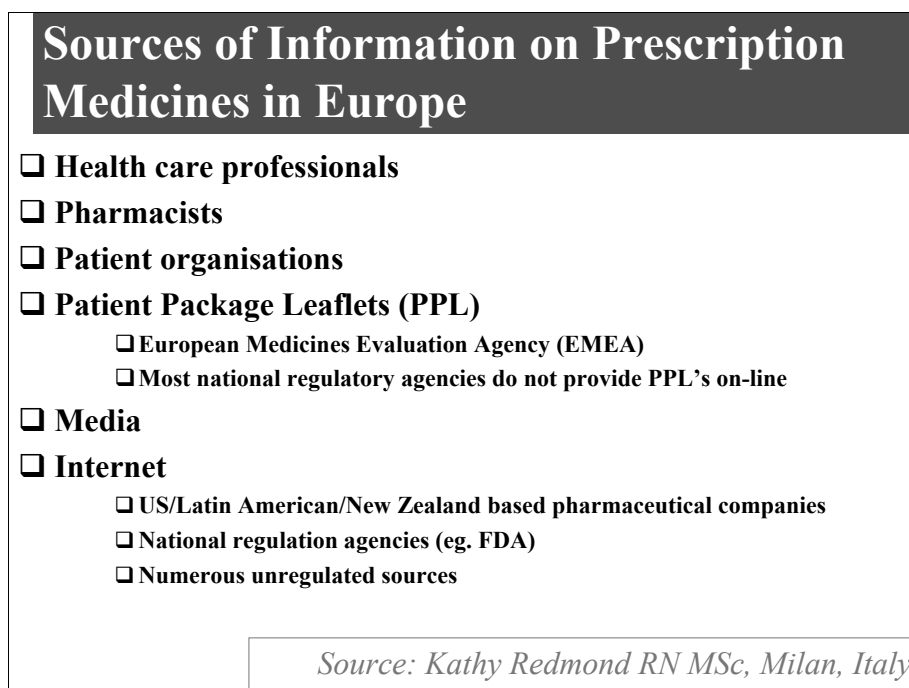
Kathy Redmond has extensive clinical experience in cancer care. Between 1988 and 1998, she was a lecturer in cancer nursing at the School of Nursing and Midwifery, University College Dublin.

In 1997, Kathy Redmond completed a four-year term as President of the European Oncology Nursing Society (EONS), and served on many of the society's committees. In addition to her international activities, she serves as a member of the Board of the Council and Education Committee of the Federation of European Cancer Societies (FECS), a member of the Board of the International Society for Nurses in Cancer Care (ISNCC), and as a member of the Scientific Committee of the European School of Oncology (ESO). She was a member of the European Commission's "Europe Against Cancer" programme. She was appointed by the Irish Minister of Health to serve as a member of the National Forum on Cancer Services, and has served as President, Secretary and as a member of the National Executive Committee of the Irish Association for Nurses in Oncology.

Kathy Redmond has been a champion of the rights of cancer patients—particularly their right to information and their right to be involved in medical decision-making about their treatment. She has written numerous articles on the topic and has spoken extensively at key European oncology meetings on ways of promoting patient choice.

Ms Redmond moved to Milan in 1998, where she works as a consultant for cancer patient and professional organisations, as well as for the pharmaceutical industry. She writes a regular feature for the recently-launched scientific magazine, *CancerFutures*, on issues surrounding cancer drug approval and access. In 2001, she was awarded the EONS Distinguished Merit Award in recognition of her contribution to the development of cancer nursing in Europe.

Figure 2.1



### Where patients currently obtain information

Patients in the EU currently obtain their information on prescription drugs from a variety of sources, some of which are more reliable or useful than others [see Figure 2.1, above]. Healthcare professionals and pharmacists, Ms Redmond noted, “do not always provide patients with the information they need at a particular moment in time”. Patient package leaflets (PPLs), though accurate, are not readily intelligible to large numbers of patients. Information produced by the media, meanwhile, is limited in depth and breadth, and tends towards the sensationalist. Finally, the Internet, while an enormous source, leaves much to be desired. For example, information on websites may not be valid outside the home country, and much of it anyway comes from unregulated sources. Nor are PPLs available online, except in a few instances.

To illustrate how information on a specific drug can differ depending on the source, Ms Redmond used the example of Tamoxifen, a leading breast cancer drug [see Figure 2.2]. She looked at information contained on three different websites: nolvadex.com (a US-based commercial website for Tamoxifen), and the websites of CancerBACUP and Breast Cancer Care (two UK-based cancer information services).

One of the key, and surprising, differences between the US site and the other two is that statements made on the commercial site are much more guarded [see Figure 2.3]. Critics of direct-to-consumer advertising of prescription drugs have stated that such commercial websites are overtly promotional in nature. Yet the literature on novaldex.com provides valuable information to patients. In addition, the safety information on the US site is more detailed than that on the two UK patient organisation sites [see Figure 2.4], allowing patients to undertake a more calculated risk-benefit analysis of the drug.

Figure 2.2

## The Reality for British Patients

Example:

- Tamoxifen
  - Thirty years of evidence has established the drug as standard care for endocrine therapy of breast cancer
  - Generic versions available
  - Substantial differences in approved indications on both sides of the Atlantic
    - Approved for breast cancer prevention in the US

*Source: Kathy Redmond RN MSc, Milan, Italy*

The key question in Europe today is whether pharmaceutical companies should be allowed to provide the same sort of information that they do in the US, tailored to each national market. Although patients worldwide can access US-based websites, the information on US sites may prove inappropriate for non-American patients. The strong US focus on Tamoxifen as a preventative treatment, for instance, is not mirrored in Europe. Hence prescription drug Internet sites need to be designed to suit national circumstances.

Figure 2.3

## Comparison between nolvadex.com and two British patient websites

- **British sites reviews:**
  - CancerBACUP ([www.cancerbacup.org.uk](http://www.cancerbacup.org.uk))
  - Breast Cancer Care ([www.breastcancercare.org.uk](http://www.breastcancercare.org.uk))
- **All sites updated recently**
- **Considerable difference in depth and breath of information provided**
- **Statements more guarded on nolvadex.com.**
  - “For most women with breast cancer, the benefits of NOLVADEX outweigh its risks...NOLVADEX can increase the risk of some serious and potentially life-threatening events.” (Nolvadex.com)
  - “There is little doubt that for most women the beneficial effects of tamoxifen far outweigh the risks” (CancerBACUP)

*Source: Kathy Redmond RN MSc, Milan, Italy*

Figure 2.4

## Contrasting Safety Information

- ❑ *“In clinical trials it has been shown that cancer of the uterus, stroke, and blood clots can occur approximately 2 to 4 times more frequently with NOLVADEX than placebo, but each occurred in less than 1% of women. Some of these strokes, blood clots, and uterine cancers were fatal...you should discuss these warnings with your healthcare provider.” (Nolvadex.com)*
- ❑ *“Studies have shown that women who take high doses of tamoxifen over a long period of time may have a very slightly increased risk of developing cancer of the lining of the womb. Blurred or reduced vision is very rare” (CancerBACUP)*
- ❑ *“There is a very slight risk of other side effects that can be more serious, including changes in your vision. There is also an increased risk of thrombosis...very rarely it causes cancer of the womb..it is important to discuss them [new symptoms] with your GP...” (Breast Cancer Care)*

*Source: Kathy Redmond RN MSc, Milan, Italy*

In Ms Redmond’s words, Europeans have “a strange situation vis-a-vis website access”. So what has been the European Commission’s attitude to factors that contrive to limit EU patients’ access to information on prescription medicines?

Figure 2.5

## The Commission’s Response

- ❑ **Given that:**
  - Provision of information on prescription medicines is sub-optimal
  - Patients have a legitimate need for information about prescription medicines
  - Demand from EU patient organisations for more and better quality information
  - Prescription medicines information is currently available on non-EU pharmaceutical companies’ web-sites
  - Need for harmonisation because interpretation of existing provisions varies significantly from one Member State to the other
- ❑ In July 2001, the European Commission proposed amending the EU’s Advertising Directive as part of the Regulatory Review package *Com(2001) 404 final*

*Source: Kathy Redmond RN MSc, Milan, Italy*

### **The Commission’s proposal**

In July 2001, the Commission proposed some amendments to pharmaceutical regulations [see Figure 2.5 above]. There were two main element to its proposal:

- A change in the definition of advertising to include the awareness of availability of medicinal products [see Figure 2.6].
- A pilot project to allow more information to be provided (under strict conditions) by pharmaceutical companies in three disease areas—diabetes, AIDS and asthma [see Figure 2.7]. These three disease areas were chosen for the reasons outlined in Figure 2.8, such as the fact that they are chronic diseases for which patients are already taking medicines.

**Figure 2.6**

**Commission’s Proposed Amendments to EU Medicines Advertising Directive**

Title VIII Advertising: Article 86

*... “advertising of medicinal products” shall include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale, consumption or awareness of the availability of medicinal products, ....*

*Source: Kathy Redmond RN MSc, Milan, Italy*

**Figure 2.7**

**Proposed Pilot Project**

- Dissemination of certain information to the public on some prescription-only medicines will be allowed under strict conditions
- Three disease areas:
  - Diabetes, AIDS and asthma (and chronic pulmonary disorders)**
- Information will comply with principles of good information practice
- Self-regulation by pharmaceutical industry
- Pre-vetting and monitoring by EMEA
- In-depth evaluation after 5 years

*Source: Kathy Redmond RN MSc, Milan, Italy*

Figure 2.8

<b>Rationale for Choosing Three Disease Areas</b>	
<input type="checkbox"/>	<b>Diseases are long-term and chronic</b>
<input type="checkbox"/>	<b>Specific patient demand for information</b>
<input type="checkbox"/>	<b>Patients with these diseases are already taking medicines</b> <ul style="list-style-type: none"><li><input type="checkbox"/> Improved information will probably not lead to increased sales of prescription medicines</li></ul>
<input type="checkbox"/>	<b>Other long-term and chronic diseases (eg. cancer, renal disease, cardio-vascular disease, neurological disorders etc.) were excluded from the pilot for fear</b> <ul style="list-style-type: none"><li><input type="checkbox"/> of overburdening EMEA</li><li><input type="checkbox"/> creating demand</li></ul>
<i>Source: Kathy Redmond RN MSc, Milan, Italy</i>	

But there were complicating factors [see Figure 2.9]. For example, the amendment to the Advertising Directive was included at a late stage of the process and caught out a number of interested parties, including the pharmaceutical industry. Ms Redmond noted that television advertising was never part of the proposal—it was already ruled out by broadcasting legislation. Not everyone on the European scene understood this. Finally, the English language version of the amendment differs from that in other languages.

Figure 2.9

<b>Complicating Factors</b>	
<input type="checkbox"/>	Advertising Directive amendments included in Regulatory Review package at very short notice (about 3 months) and without the usual consultations
<input type="checkbox"/>	TV advertisement remains banned under the broadcasting directive
<input type="checkbox"/>	The English version of the Explanatory Memorandum refers to “public advertising”. All other linguistic versions say “information to the public”
<i>Source: Kathy Redmond RN MSc, Milan, Italy</i>	

## The debate

Ms Redmond noted that the proposal opened a “polemic debate” in Europe. Supporters of the liberalisation of existing legislation said that the debate was about information. Opponents of the proposal insisted that advertising was the key variable [see Figure 2.10]. Both sides, however, agreed that the pilot study was flawed, though for different reasons.

Figure 2.10

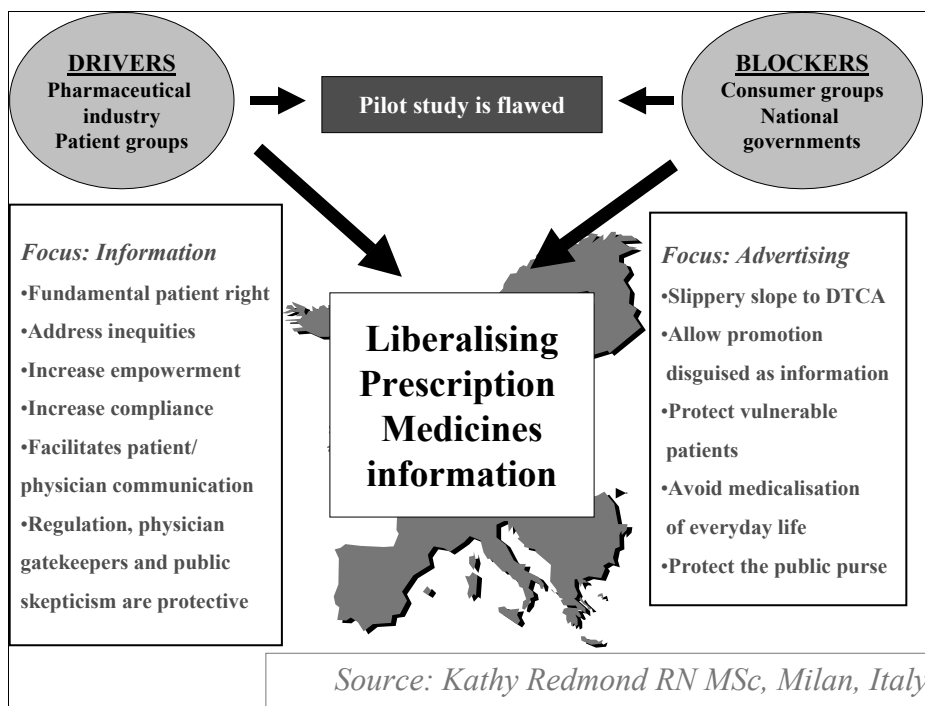
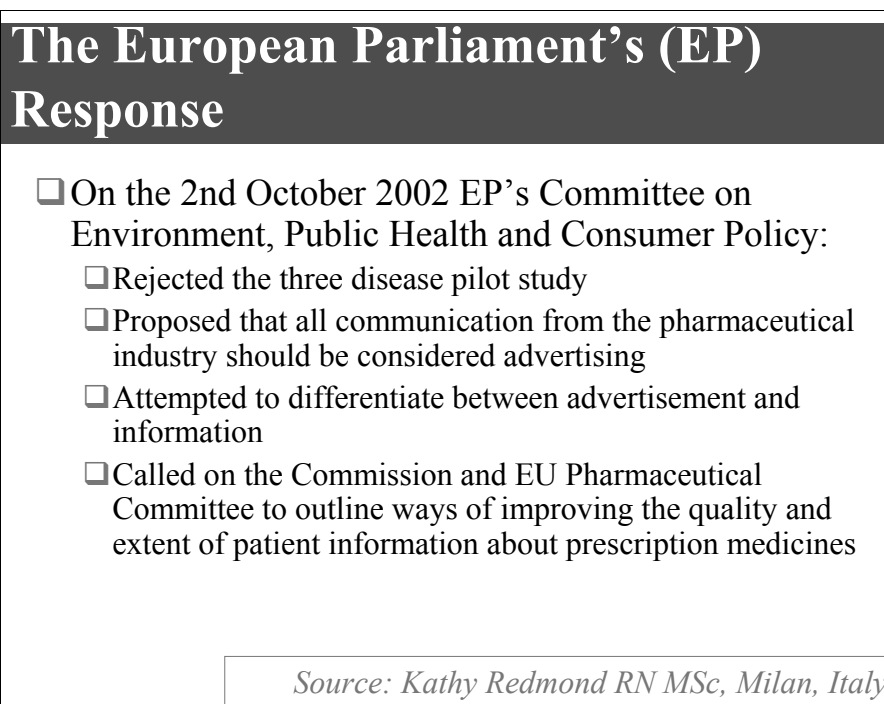


Figure 2.11

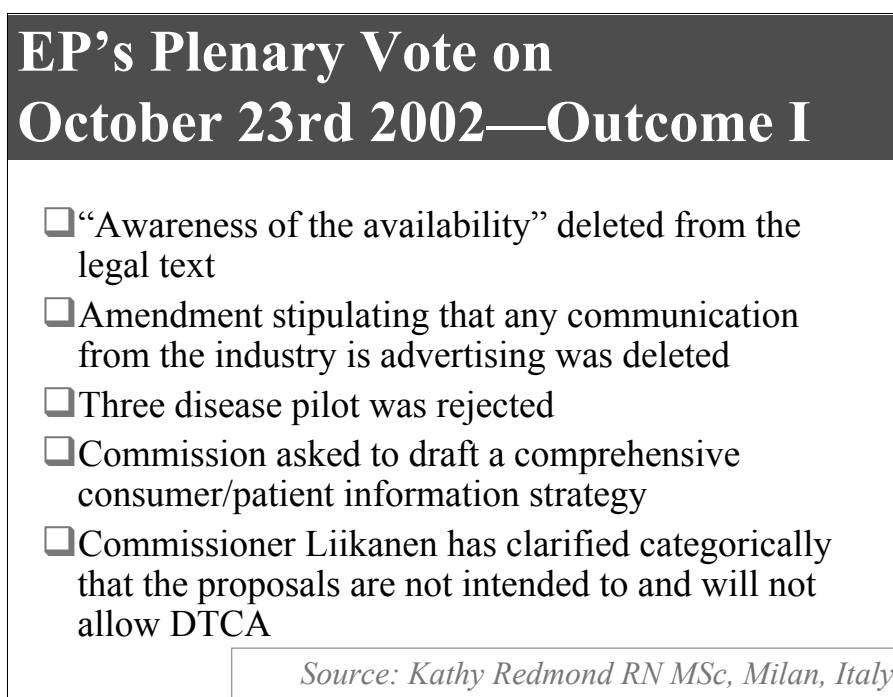


The European Parliament's response (via its Committee on Environment, Public Health and Consumer Policy) was to reject the pilot study. The Parliament also proposed that all information from the pharmaceutical industry should be considered advertising; it attempted to differentiate between information and advertising; and it called for further work to be done to outline ways to improve the quality and extent of patient information on prescription medicines [see Figure 2.11].

### The vote

The proposals were put to the vote in the European Parliament on October 23rd 2002. The outcome is shown in Figure 2.12.

**Figure 2.12**



One result of the Parliament's vote is that a proposal now exists distinguishing between information and advertising. Many would regard this as a helpful development. Even so, the form of words used is odd in places. For instance, included within the definition of information is the term “canvassing activity”—a phrase which might be thought of as a component of advertising [see Figure 2.13]. However, Parliament also proposed that patients have a legitimate need for information [see Figure 2.14].

### What next?

The legislation is now subject to the so-called ‘co-decision procedure’. EU Member States and the European Parliament will have an equal say [see Figure 2.15]. The Commission, meanwhile, is unhappy at the rejection of the three-disease pilot and would like to resurrect it. EU health ministers are expected to adopt a “common position” on the amendments by early 2003 (after which they will return to the Parliament). If no agreement is forthcoming, the conciliation procedure will come into play. The Commission wants the amendments adopted by 2004, before EU enlargement.

Figure 2.13

**EP Plenary Vote October 23<sup>rd</sup> 2002—  
Outcome II**

Title VIII Advertising and Communication of  
Information: Article 86, paragraph 1

... *‘information on medicinal products’ shall include objective reports on the composition, action, quality, indication, contra-indication and adverse reactions as well as the results of canvassing activity, and “advertising of medicinal products” shall include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale, consumption ~~or~~ ~~awareness of the availability~~ of medicinal products, ...*

Figure 2.14

**EP Plenary Vote October 23<sup>rd</sup> 2002—  
Outcome III**

Title VIIIa Information: Article 100a

*“The provision of reliable comparative information on diseases, therapeutic strategies and medicinal products is authorised in the interest of patients in order to respond to their legitimate needs.”*

In parallel with the legislative process, consultations are taking place with patient organisations and other interested parties [see Figure 2.16].

Interestingly, very little debate about the proposals have taken place at national level, even though they will impact on patients throughout the EU [see Figure 2.17]. In the UK, for example, where the advertising directive is interpreted quite liberally at present, a risk exists that current practices with regard to DTCI will be curtailed when the legislation is amended. Most member states, Ms Redmond noted, would rather see no change in the legislation, fearing an increased supply of prescription drug information to the public would result in greater national healthcare expenditures.

Figure 2.15

## Next steps—Legislation

- Co-decision procedure**
  - Member States and EP have equal say**
- Commission will revise legal text to include EP amendments**
  - Commission Official stated that it will pursue pilot in a different form despite EP rejection**
- Member States expected to adopt their “common position” first half 2003**
- Followed by Second Reading of EP and Council end-2003**
- Conciliation phase 2004**
- Aim: Final adoption 2004 before Enlargement**

*Source: Kathy Redmond RN MSc, Milan, Italy*

Figure 2.16

## Next Steps—Parallel Consultations

- In parallel Commission consultation with patient organisations and other interested parties to produce comprehensive patient/consumer information strategy**
  - Opportunity for patients to make their voice heard**
- EU Pharmaceutical Committee Working Group on Information to establish quality standards**
  - First Stakeholders meeting 24 September 2002**
  - Next meeting planned December 2002**

*Source: Kathy Redmond RN MSc, Milan, Italy*

Patients therefore need to make their views known at the national level. Ms Redmond called on key Member States such as the UK, Sweden, the Netherlands, Italy and Germany—all relatively large countries in which legislation is more liberal—to take the lead in Council discussions.

Figure 2.17

### Next Steps—Discussion at National Level

- So far little debate at national level**
  - Focus has been on advertising, not on quality of patient information
- So far no discussion has taken place on this section in the Council working group**
  - Most Member States prefer the status quo
  - Little support for 3 disease pilot
  - Government's concern is increase in medicines bill
- Need for patient groups to make their view known to their governments**
- Need for some key Member States to take the lead in Council discussions (UK, Sweden, NL, Italy, Germany)**

*Source: Kathy Redmond RN MSc, Milan, Italy*

## Conclusion

Ms Redmond concluded that the provision of patient information on prescription medicines in Europe could be significantly improved. Unfortunately, the legislation proposed by the Commission in 2001 to rectify the anomalies in the supply of prescription drug information generated a very polarised debate. Nonetheless, patient expectations about improvements in the extent and quality of information of prescription drug information have been raised. It is far from clear that the proposed legislation voted in by MEPs on October 23rd 2002 will address the European prescription drug informational gap with the US. What is certainly clear is that a far less polarised debate between patients, consumers, insurers, governments and the pharmaceutical industry is required.

## Key dates in the EU timetable

**July 18th 2001:** Amendments to EU legislation on DTCI on pharmaceuticals proposed by the European Commission, including three-disease pilot study.

**October 2nd 2002:** The European Parliament's Environment Committee amended the Commission's proposal. Called for the restriction of almost all forms of communication between the pharmaceutical industry and the public on prescription medicines.

**October 23rd 2002:** European Parliament voted to reject the three-disease pilot. But acknowledged patients' right to information and called for more consultations.

**Early/mid 2003:** EU health ministers expected to adopt common position on revised legislation.

**Second half 2003:** Second reading of legislation by European Parliament.

**2004:** Conciliation phase (if necessary), followed by final adoption.

## Questions and answers

### **Patient groups versus consumer groups**

Kathy Redmond's presentation generated several questions and comments about the aims and objectives of consumer organisations versus patient organisations, and about the organisation of patient groups at national and EU level. For example, one participant noted that the voices of consumer groups tends to be louder than those of patient groups, and that the two do not necessarily want the same things. Consumer groups, for example, have tended to side with the anti-globalisation argument.

Ms Redmond agreed, noting that the Consumers' Association in the UK has tended to focus the debate on advertising, not information, and as such has set itself up against the pharmaceutical industry. She noted that consumers may have different views to patients on matters such as treatment. As witnessed in the field of cancer, it is not until someone has an illness that they are truly confronted with the issues.

It was noted that patient groups are not as well organised at the EU level as they are at the national level. Albert van der Zeijden of the International Alliance of Patients' Organizations (IAPO) suggested that the outcome of the recent European debate on direct-to-consumer prescription drug information might have been much more effective if fewer patient organisations took the role of representing the hundreds of thousands of patient groups that exist in the EU.

### **Information versus advertising**

One participant questioned whether it was possible to distinguish between information and advertising. This attendee mentioned the US experience, where drug spending has gone up sharply following the liberalisation of advertising rules. Europe's poorly-funded health systems might worry about the post-DTCA increase in drug spend in the US.

Ms Redmond, while pointing out that the US experience involved direct-to-consumer advertising, not the direct-to-consumer information proposed in Europe, did agree that the amount spent in the US on advertising drugs to consumers had increased. She argued, however, that the extra money had been shifted from other areas of drug company budgets (such as marketing to health professionals). Moreover, other factors are also putting pressure on European health budgets, such as ageing populations.

### **Access to information**

On the issue of online information, one participant drew attention to the divide between the most needy in society and those with access to information.

Ms Redmond agreed that the digital divide needs to be addressed in Europe.

## Chapter 3

# Publicly available prescription drug information in the UK

*The UK supplied the greatest number of patient group responses to the PatientView/IAPO EU-wide survey published in June 2002. The UK respondents tended to be long-established and involved in a wide variety of disease areas. The survey results also showed that British patients were sceptical about the value of prescription drug information from certain sources. British patients also wanted pharmaceutical companies to supply them with more data directly, so that they could negotiate their treatment options with GPs. But UK respondent patient groups insisted that if industry-sourced prescription drug data were supplied direct to the public, it would need to be tightly regulated.*

## **Albert van der Zeijden**

**Chairman, International Alliance of Patients' Organizations,  
and Vice-Chairman, the Council of the Chronically Ill and the Handicapped in the Netherlands**

Mr van der Zeijden's background is in psychology and teaching. Until 1980, he was a teacher and director of a college. Until 1988, he was member of the board and chairman of a teacher training college.

Since 1982, Mr van der Zeijden has been active as a board member of patient organisations. His involvement is on both a national and an international level. At present, Mr van der Zeijden is Vice-Chairman of the Council of the Chronically Ill and the Handicapped in the Netherlands (CG-Raad). CG-Raad is an umbrella organisation, representing more than 130 national associations of people with a long-term medical condition or a disability. He is also Chairman of the first global patient organisation, the International Alliance of Patients' Organizations (IAPO).

Mr van der Zeijden is a member of the board of numerous organisations, including: the Dutch Council for Health Research; "The Week of the Chronically Ill" Foundation; the Advisory Committee of International Experts of the European Health Forum Gastein; the patients' research centre, "Patients' Practice" (Patiënten Praktijk); and the European Health Policy Forum (DG Sanco).

Mr van der Zeijden was born in 1941. In 1980, he was diagnosed as having Crohn's disease and ankylosing spondylitis.

## **Alexandra Wyke** *[speaker and panel member]*

**Managing Director, PatientView**

Dr Alexandra Wyke is the Managing Director of PatientView, a research and publishing

**Figure 3.1**



organisation founded by her in 2000. As Managing Editor, she set up and ran a successful healthcare publications division at the Economist Intelligence Unit between 1996 and 2000. From 1983 to 1996 she was healthcare correspondent for *The Economist*.

In 1996, Dr Wyke was a member of a BBC panel with a responsibility to assess the Corporation's science coverage. She is the author of *21<sup>st</sup>-Century Miracle Medicine*, published by Plenum in 1997. Dr Wyke is a member of the Health Management Initiative Advisory Board, INSEAD. She holds a PhD in biochemistry from St George's Medical School, London.

### **About IAPO**

Albert van der Zeijden began by saying that IAPO is a "young organisation", having been founded in 1999. It brings together patients from all over the world and is the only disease-crossing organisation that covers global healthcare subjects, ranging from patient education to end-of-life issues. IAPO's main tool is its patient network.

The organisation's aim is a simple one: to make healthcare patient centred. This, however, is a complex task to fulfil, involving a range of issues, such as social inclusion and educating physicians. Mr van der Zeijden noted that "better information is the key to better communication". However, information in itself has no power.

### **About the PatientView and IAPO collaboration**

Against this background, IAPO was interested to know what patients really thought of the Commission's proposed amendments to EU pharmaceutical legislation on prescription drug information. As a result, IAPO was pleased to work with PatientView on its survey of patient groups [see Figure 3.1].

### Why conduct a survey on DTC prescription drug information?

Alexandra Wyke noted that the PatientView/IAPO survey was the first EU-wide study carried out among patient groups across virtually all disease areas. She added that the level of response was surprisingly high, given the fragmented nature of EU patient groups. The highest response rate in the original EU-wide survey came from the UK [see Figure 3.2]. This is perhaps less surprising; the country has one of the longest-established patient advocacy movements in Europe.

**Figure 3.2**

**Why was the survey conducted?**

1. As part of an EU-wide initiative to provide on-the-ground information relevant to the EC's proposals for DTCI (as they stood on July 2001). Patient groups in the UK produced the highest number of responses to the initiative.
2. The analysis allows UK patient groups to express their opinions on a wide range of topics regarding the quality of—and access to—prescription drug information.
3. The data also gives patient groups greater leverage in future policy-making discussions at national and EU levels.

Source: PatientView's DTCI survey of UK-based patient groups, 2002  
Conducted in collaboration with The International Alliance of Patient Organisations

Various steps were taken to ensure that the report was independent of vested interests and representative of patient organisations [see Figure 3.3]. Patient groups were screened, to eliminate, for example, those solely dependent on drug industry funding. Patient groups were also asked to contribute anonymously, though they could have their names listed in an appendix if they wished (around half of the respondent groups agreed to this).

Over 80% of the UK groups that responded to the survey said they were expressing the views of their organisation or the views of patients with whom they were familiar [see Figure 3.4]. Prior to conducting the survey, no one knew whether, and to what extent, patient groups had discussed the issue of direct-to-consumer information on pharmaceuticals. The survey results showed that a large proportion of groups felt confident enough about the subject to speak on behalf of others.

Figure 3.3

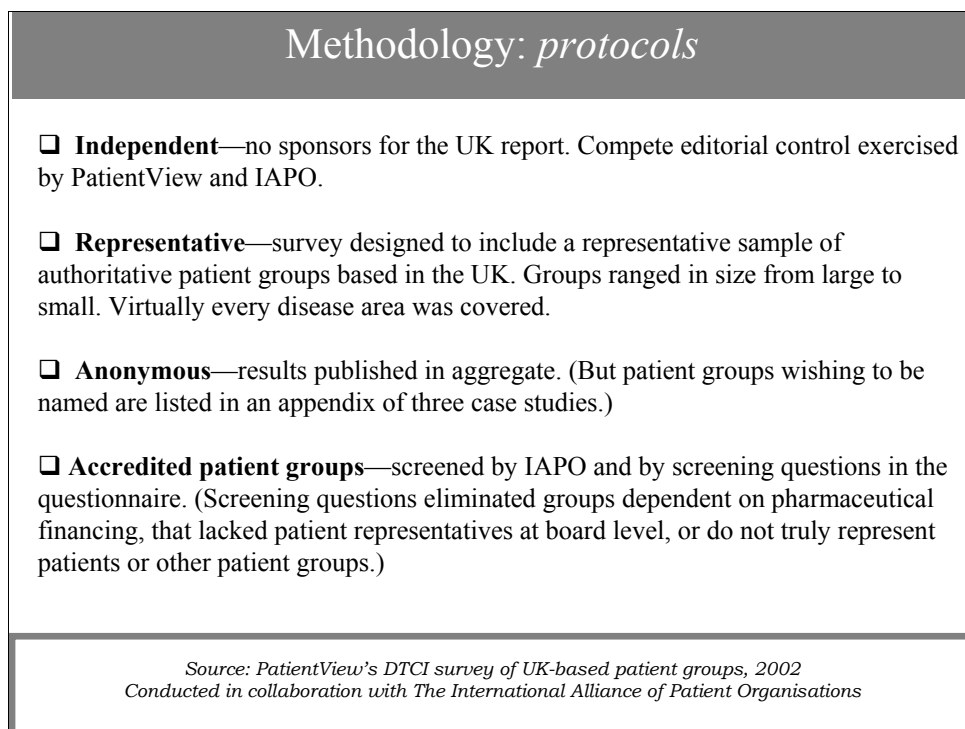
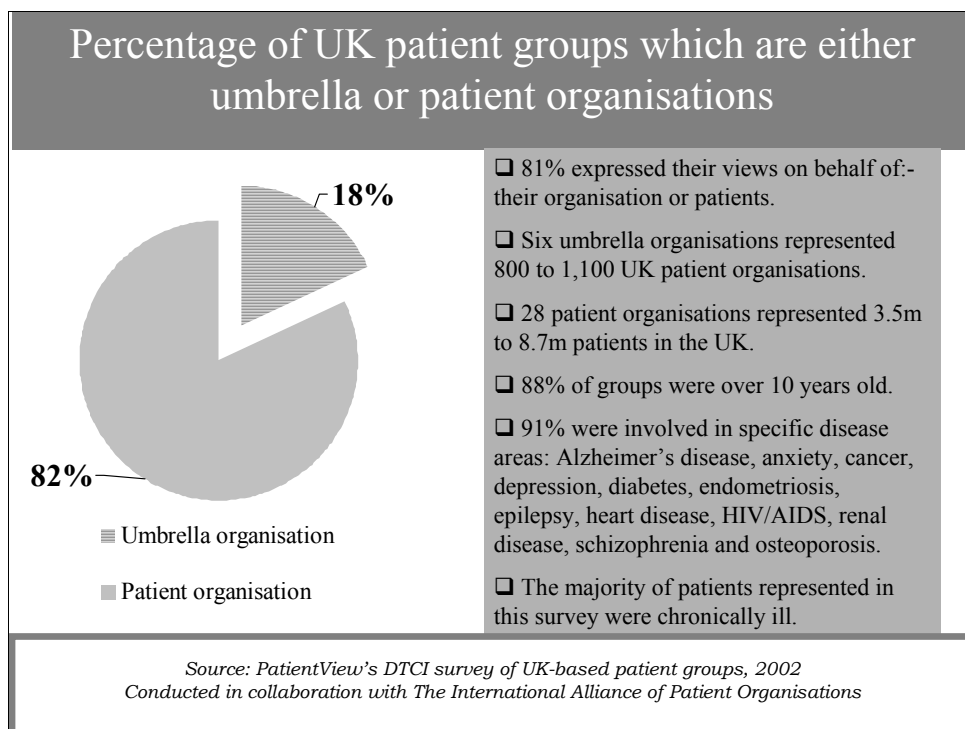


Figure 3.4



Although primarily concerned with patient organisations' opinions on direct-to-consumer prescription drug information (DTCI), the survey also threw up some intriguing facts about the respondent patient groups themselves and their operations [see Figure 3.5]. For example, UK groups received less government funding than their counterparts in the rest of the EU. Also, UK groups were more likely to have an EU-wide focus than patient groups located in other European countries.

**Figure 3.5**



### **The survey findings**

As noted in Kathy Redmond's presentation, patients obtain their information on prescription drugs from a range of sources [see Figure 3.6]. One interesting finding from the PatientView/IAPO survey was that only 53% of patients in the UK get most of their prescription drug information from doctors. A higher percentage might have been expected.

Also surprising was the fact that only half of UK patients trusted doctors to provide information on prescription drugs [see Figure 3.7]. As such, UK patients were less trusting of doctors than EU patients in general. One reason for the lack of trust, Dr Wyke argued, is that doctors are constrained by having to juggle their two conflicting roles in the healthcare system—a need to stay within budget, versus an instinctive desire to do the best for patients.

Pharmacists were trusted more in the UK than was generally the case in the EU.

Figure 3.6

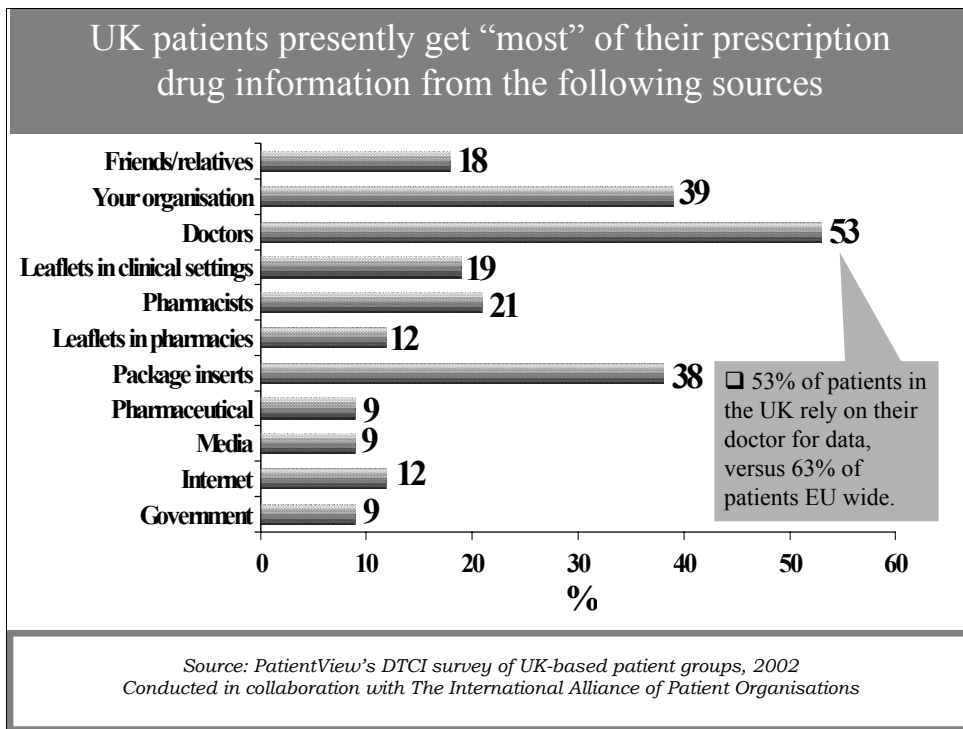


Figure 3.7

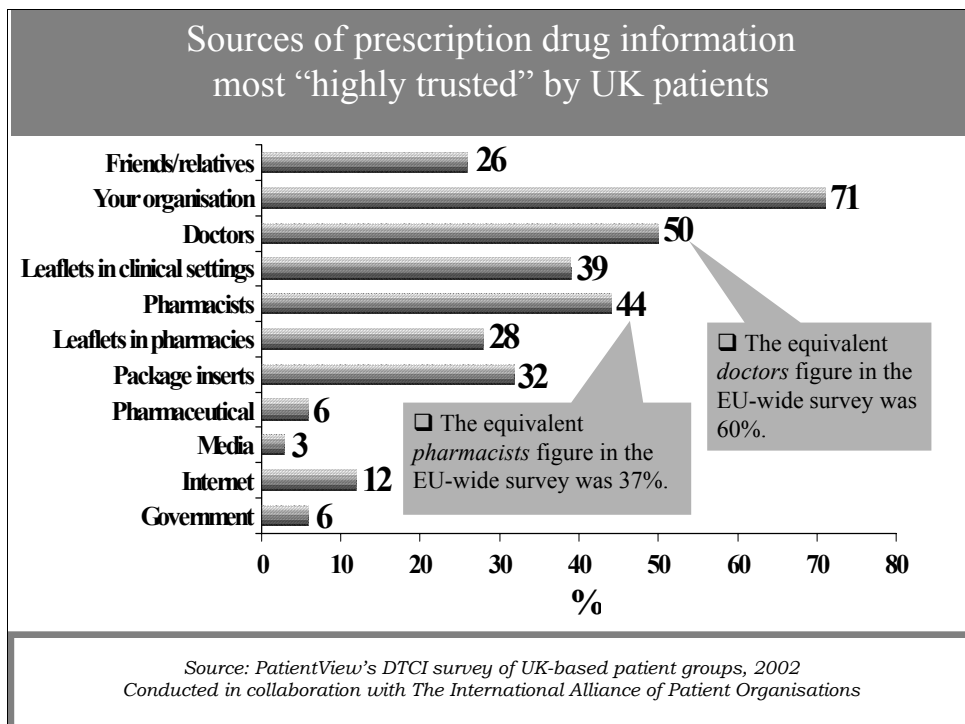


Figure 3.8

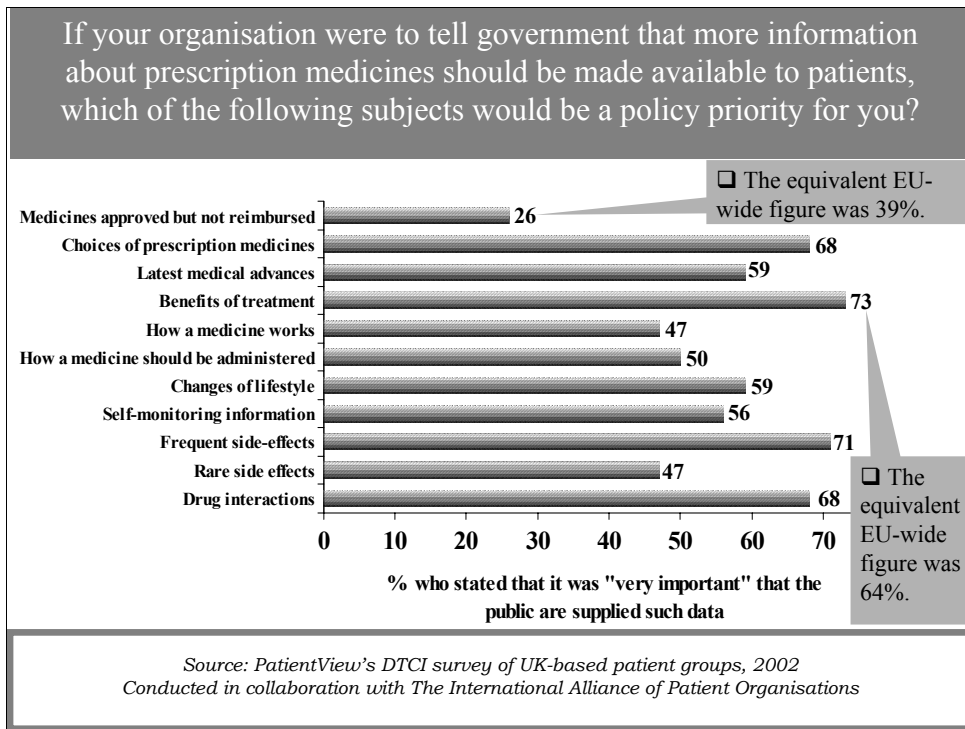
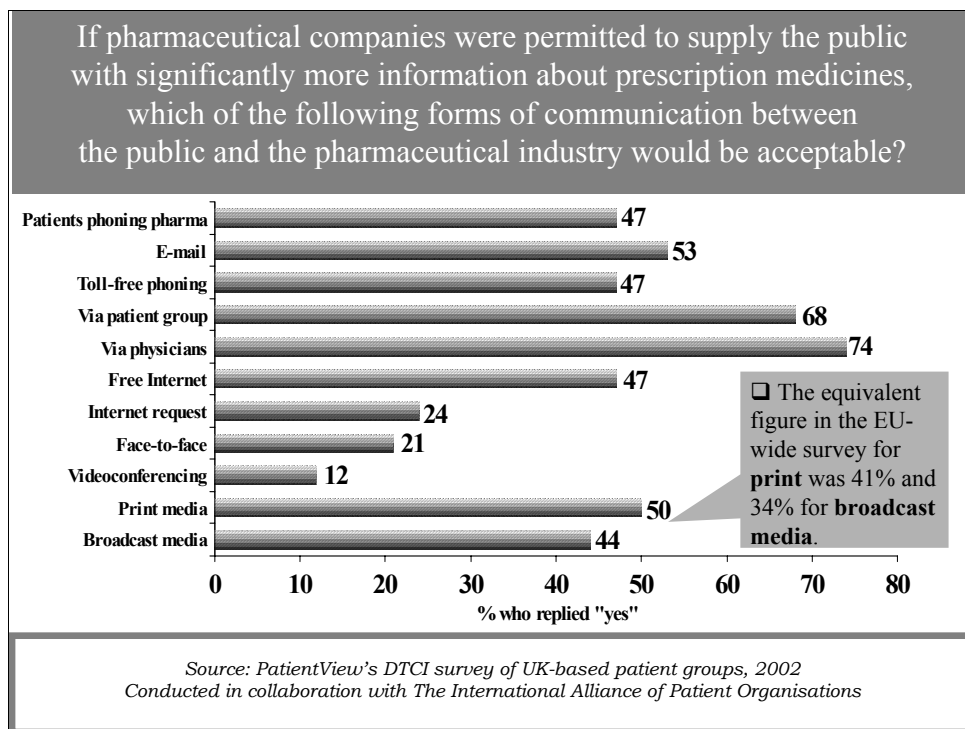


Figure 3.8 shows that patients have many priorities for more information on prescription medicines.

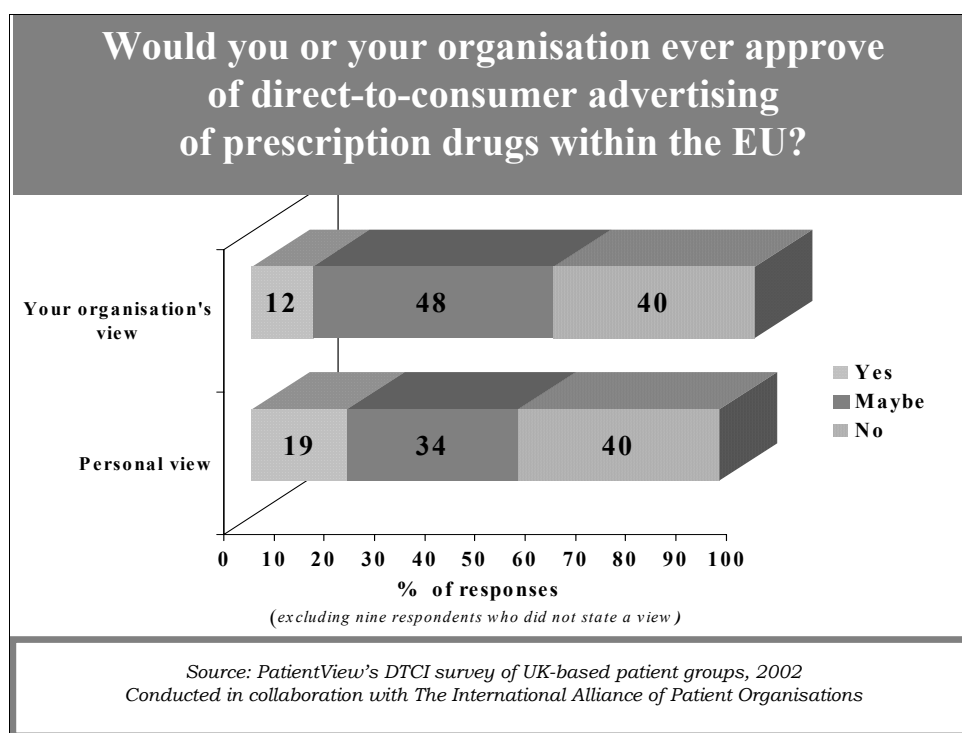
Figure 3.9



A question examining the form that permissible communication between pharmaceutical companies and the public might take [see Figure 3.9] produced a fascinating result. Although the Commission has concentrated on promoting the increased dissemination of prescription drug information via the Internet, patients and patient groups still prefer to gain most of their information from doctors. Patient groups are also considered an important and reliable source of drug data. The problem at the moment is that patients do not feel they are getting enough prescription drug information from any source.

When UK patient groups were asked whether or not their organisation would ever approve of direct-to-consumer advertising of prescription drugs within the EU, such is the dearth of prescription drug information that less than half said “no”. Yet, during the later discussions at the High-Level Forum, the general sentiment of attendees was that direct-to-consumer prescription advertising was unsuitable for patients in Europe.

**Figure 3.10**

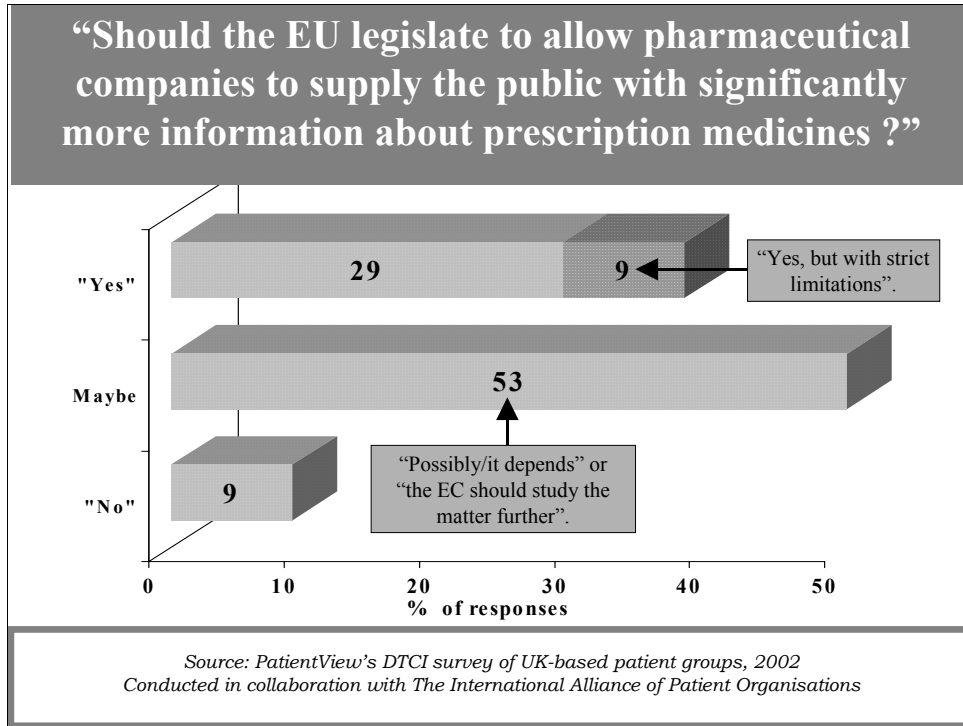


On the question of whether the EU should legislate to allow drug companies to supply the public with significantly more information about prescription medicines, Dr Wyke noted that UK groups were more cautious than EU patient groups in general [see Figure 3.11]. Patient groups answering “no” to this question tended to do so because they themselves were already providing patients with a considerable amount of information about medicines.

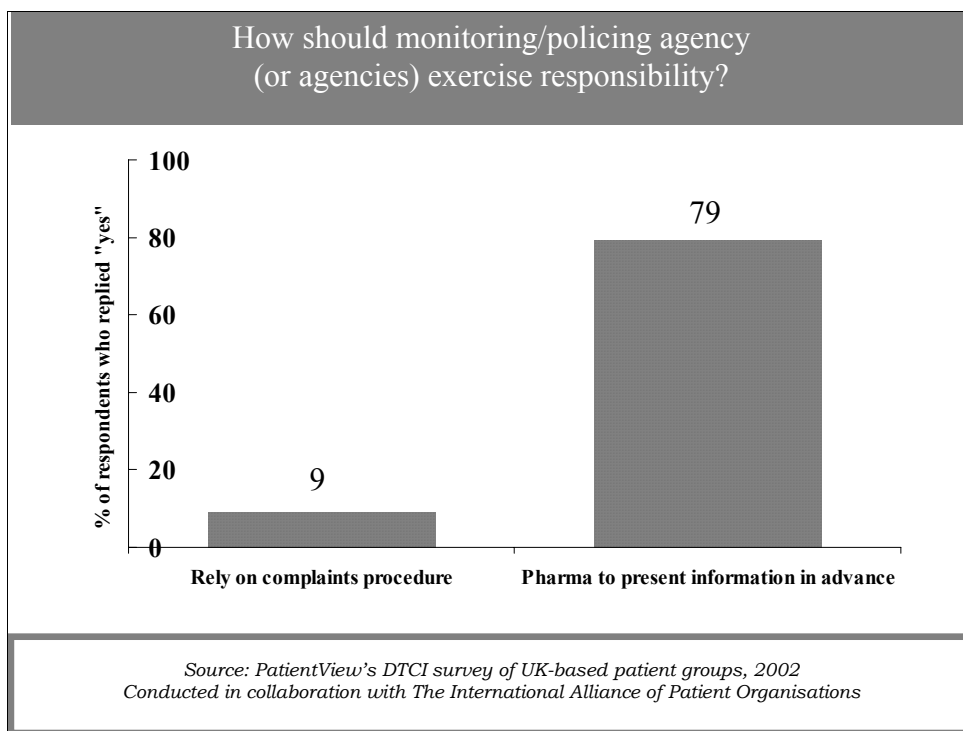
One of the survey’s seminal findings was that patient groups believed that the supply of information on prescription medicines from pharmaceutical companies should be strictly controlled. The UK respondents, in particular, felt that all prescription drug information supplied by companies should be pre-vetted [see Figure 3.12]. Dr Wyke also noted the

low level of awareness in the UK (and, more generally, in the EU) about the existence and activities of the London-based European Medicines Evaluation Agency (EMA), the body favoured by the European Commission to conduct the vetting.

**Figure 3.11**



**Figure 3.12**



## Questions and answers

### **Are patient groups representative of patients?**

One participant asked whether patient groups are truly representative of patients. Dr Wyke noted that people with chronic diseases tend to be drawn to patient groups; therefore, in the context of the PatientView/IAPO survey, the answer to that question would inevitably be “yes”.

Patient group representatives attending the Forum added their own answers to this participant’s question. Attendees gave examples of how they have built up infrastructure and knowledge bases, such as branch networks. These structures, they believed, enabled them to speak for patients with authority. Attendees also made the point that even when the membership of individual patient organisations only accounted for a small proportion of the total patient population that they claimed to represent, the percentage becomes far higher over the course of time. This is because members come and then go—over time, people become sick, get better and no longer need to use the resources of the patient group.

### **What sort of prescription drug information should be supplied to patients?**

Questions were raised about pitching prescription-drug information at the right level—neither patronising nor worrying to patients. One patient group representative said that PPLs, for instance, got the balance wrong—some patients were frightened by the side-effects listed in PPLs. Indirectly, therefore, PPLs might arguably produce exactly the opposite effect on some patients to that which they were designed to do—PPLs can contribute to non-compliance, instead of reducing it. The point was made that some patients even stopped taking medication after reading their PPLs.

Albert van der Zeijden stated that patients with uncommon diseases almost invariably tend to know a lot about their conditions—often, they are better informed than even their doctors. These patients are hungry for still more information. But this level of desire for treatment information is not always found in patients in general. He agreed that non-compliance is a major problem in many disease areas.

### **Communicating the information**

One patient group’s representative noted an item of research from that particular patient group. The attendee said that some patients favoured mediators as communicators of information—such as pharmacists and specialist nurses. The attendee suggested that more account of mediators should have been taken in the PatientView/IAPO study. Dr Wyke agreed.

## Chapter 4

# The Medicines Partnership

*Joanne Shaw, director of the UK-based Medicines Partnership, described this relatively new task force. The Partnership was formed with the intention to improve drug compliance by promoting drug concordance. In effect this means that patients need more access to prescription drug information.*

## **Joanne Shaw**

### **Director, Medicines Partnership**

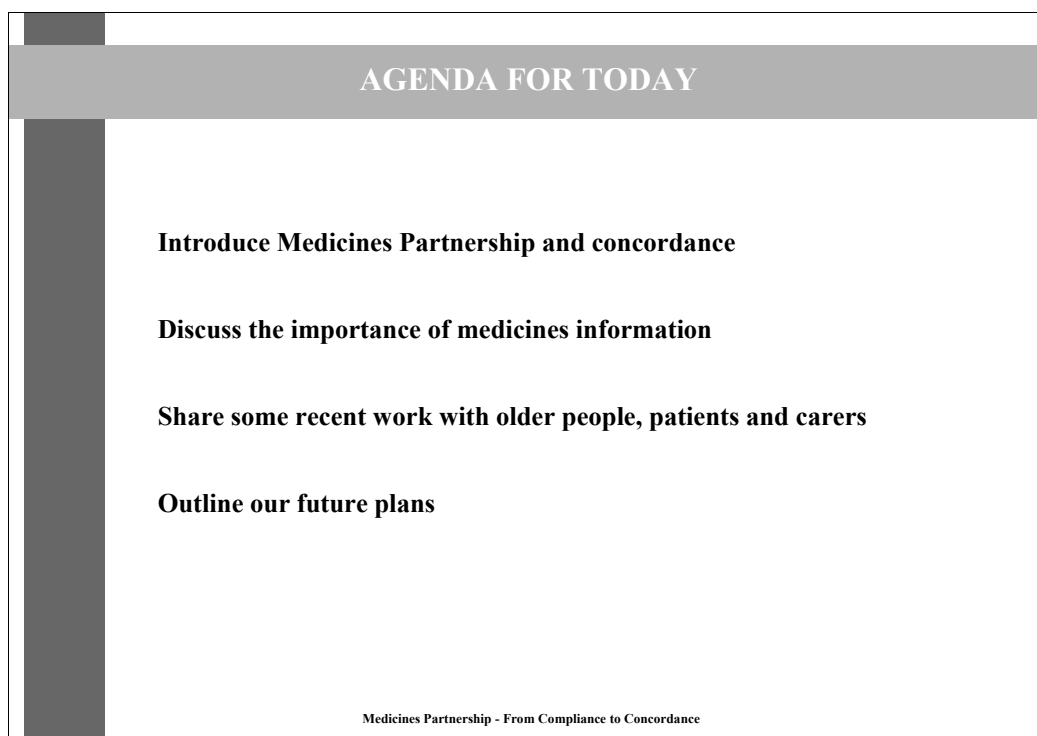
Ms Shaw is an expert on change management, with a longstanding interest in prescribing issues and the use of medicines. She is Director of the Task Force on Medicines Partnership. Medicines Partnership is a Department of Health-funded programme intended to improve the way medicines are used in the UK National Health Service (NHS). The programme focuses on how the concept of partnership between patients and prescribers can be put into practice to improve patients' health and quality of life, and to make better use of scarce NHS resources. The team which Ms Shaw leads is based at the Royal Pharmaceutical Society and works closely with leading figures from the professions, patient groups, the NHS and industry.

Ms Shaw previously held the post of Director of Performance Development at the Audit Commission. Her remit there was to lead work on modernising the Commission's own processes and approaches—focusing particularly on the Commission's role in supporting the improvement of public services. She also directed a programme of research and publications on aspects of change management. She joined the Audit Commission's Health Studies directorate in 1996 to lead a variety of projects on the NHS, including: prescribing; accident and emergency care; information management; and the ambulance service.

Before joining the Audit Commission, Ms Shaw was a strategic management consultant, specialising in healthcare and the management of change. Much of her time was spent with major international pharmaceutical companies, covering both global research and development processes, and sales and marketing in the UK. Her work involved helping pharmaceutical companies to better understand the needs of patients and clinicians, and supporting them to develop more constructive relationships with the NHS at all levels.

Ms Shaw originally trained as a chartered accountant and management consultant. Her areas of interest were health and central government policy, and strategy development for voluntary and non-governmental organisations in the UK and the developing world.

**Figure 4.1**



### **About concordance**

The Task Force on Medicines Partnership, Joanne Shaw explained, was formed as a result of concern that a large proportion of patients were not taking their medication in accordance with the recommendations supplied by manufacturers. In other words, the levels of non-compliance among UK patients is high. Non-compliant patients suffer a loss of clinical benefits. For the UK's NHS, non-compliance is expensive. Patients remain sick or suffer from preventable complications and the costs of healthcare rises. Pharmaceutical companies are also adversely affected; their medicines may appear less effective to patients (and to the patients' doctors) than is really the case [see Figure 4.2]. To address the problems of non-compliance, patients need to be involved when treatment decisions are taken. A new approach to prescribing is needed, one that more fully involves patients. The Medicines Partnership approach, which was described by Ms Shaw, relies on greater "concordance", taking a shared approach between doctor and patients).

### **About the Task Force on Medicines Partnership**

To illustrate the extent of non-compliance, Ms Shaw provided two examples taken from the medical literature [see Figure 4.3]. In the first example, a Canadian study published in 1979, around half of the patients studied were shown to be non-compliant with their recommended drug regimen. The second study, published in 1989, involved kidney transplant patients. The results were even more alarming. Nearly one-fifth of patients did not take the immuno-suppressants they were prescribed—even though these drugs were probably the patients' only guarantee that their bodies would accept the kidney implant graft. Although both studies were conducted a number of years ago, more recent work suggests that the situation regarding patient compliance with treatment has not improved either abroad or in the UK.

**Figure 4.2**

**MEDICINES PARTNERSHIP**

**Sub-optimal use of medicine is a serious problem**

- For patients
- For the NHS
- For the pharmaceutical industry

**Patients' beliefs and goals are a key influence on medicine-taking**

**Concordance is a new approach that involves patients as partners in prescribing decisions**

**Medicines Partnership is an opportunity to implement concordance**

Medicines Partnership - From Compliance to Concordance

**Figure 4.3**

**NON-COMPLIANCE REMAINS A MAJOR ISSUE**

**Compliance tends to converge to approximately 50% irrespective of:**

- Medication regime
- Illness
- Treatment setting

*(Sackett 1979)*

**Renal transplant patients offer a dramatic example *(Rovelli 1989)***

- 18% did not take medicines as prescribed
- 91% rejected the kidney or died, compared with 18% of those who took medicine as prescribed
- 80% of rejections directly related to patients not following medication advice

Medicines Partnership - From Compliance to Concordance

Figure 4.4

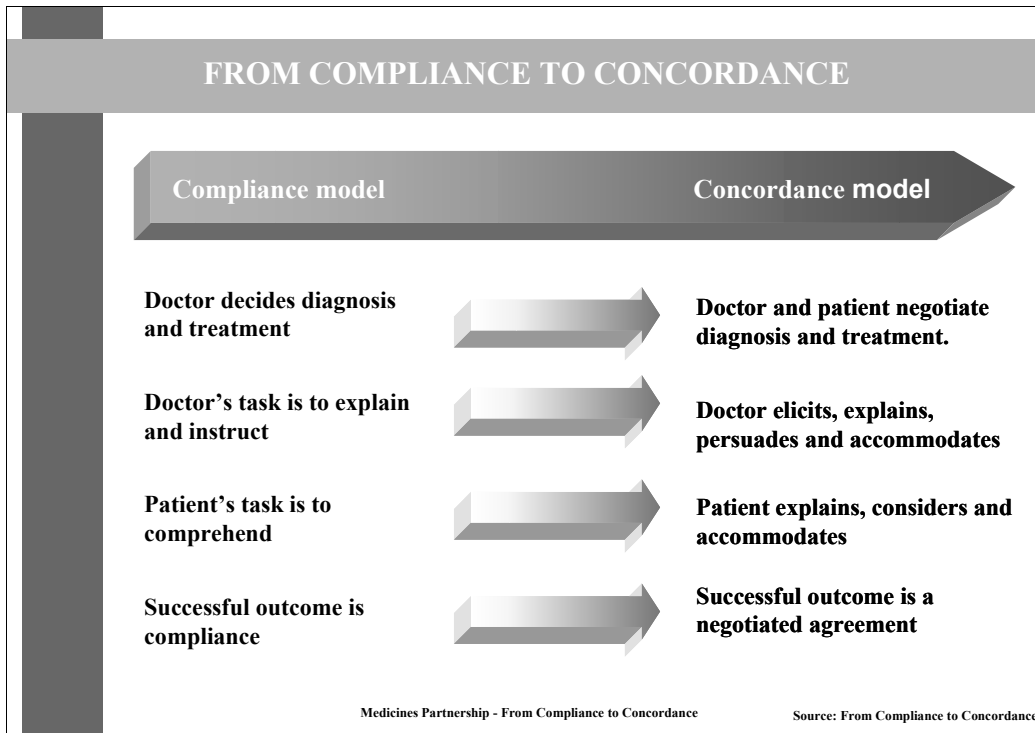
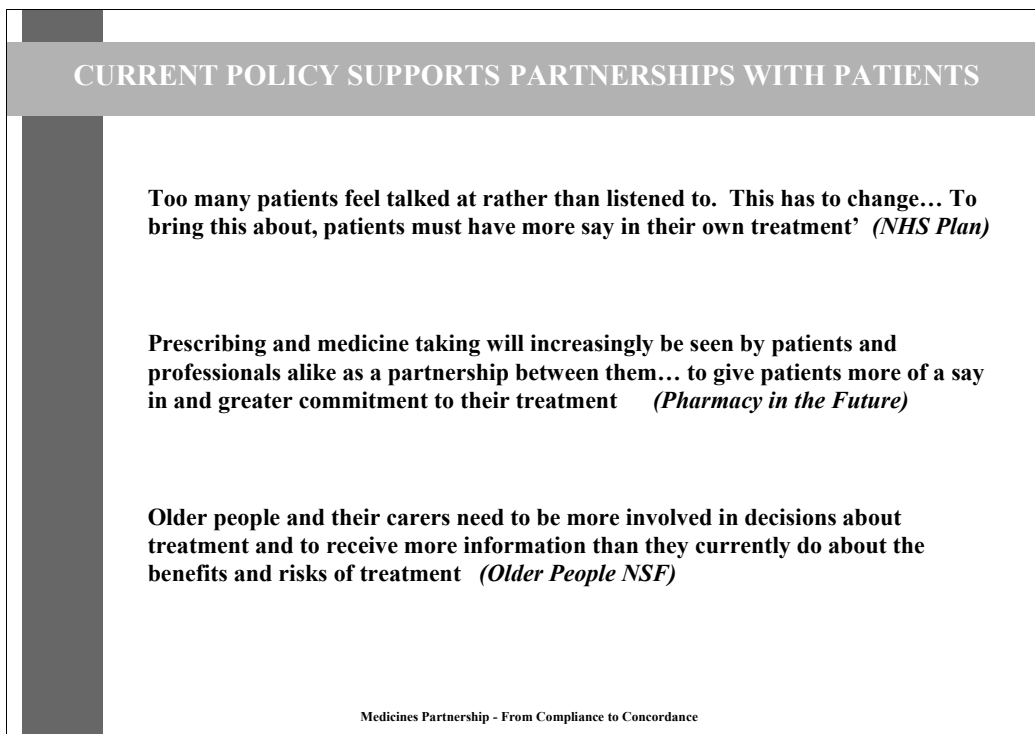


Figure 4.5



### From drug compliance to concordance

The ‘old’ compliance model of treatment [described in Figure 4.4] misses the fact that the patient is a decision maker and must consent to treatment. The new model of concordance [described in Figure 4.4] attempts to create a sense of partnership with the patient in the decision-making process that leads up to treatment. For the doctor, the relationship with patients is very different.

The Task Force on Medicines Partnership, which advocates the promotion of concordance, is part of a wider effort to make the NHS more patient-centred. Patients are more greatly involved in decisions about treatment [see Figure 4.5 and Introduction].

**Table 4.1 Task Force on the Medicines Partnership**

NHS	Patient groups	Practitioners	Academics
Royal Pharmaceutical Society	Pharmaceutical industry	Department of Health	Professional bodies

*Source: Medicines Partnership 2002*

Patient and public involvement in the new NHS works on several levels [see Figure 4.6 and Figure 4.7]. Those at the peak of the pyramid take the strategic decisions, based on the feedback received from patients—the process that takes place in the middle-tier of the pyramid. At the bottom of the pyramid, individual patients need to have a greater say in their own treatment.

**Figure 4.6**

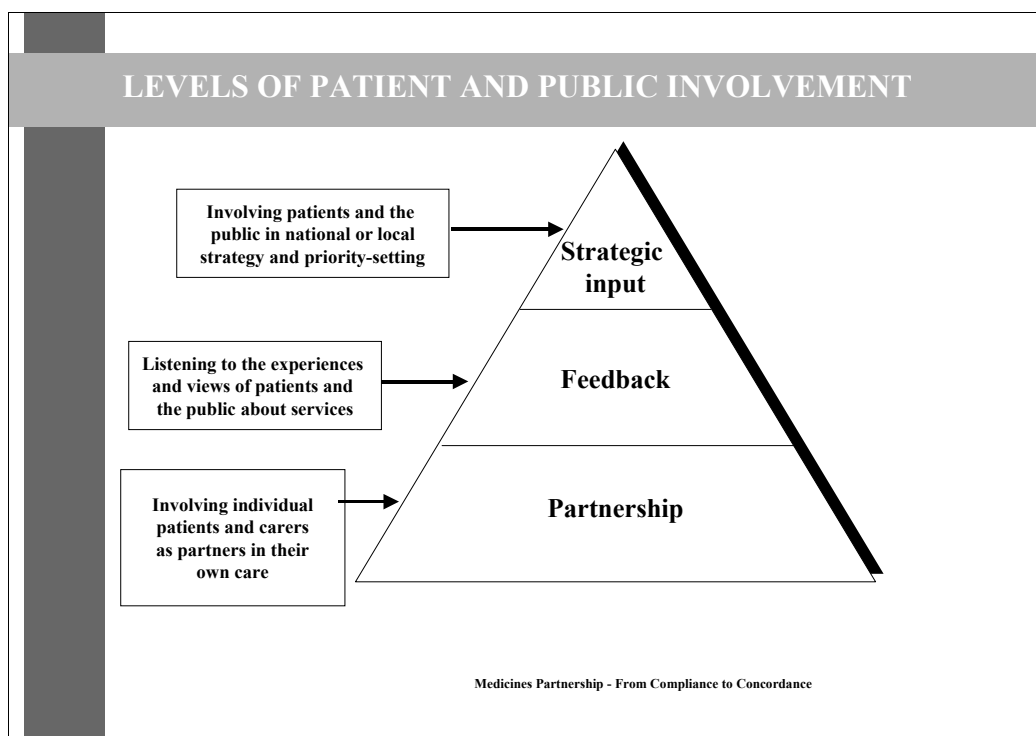


Figure 4.7

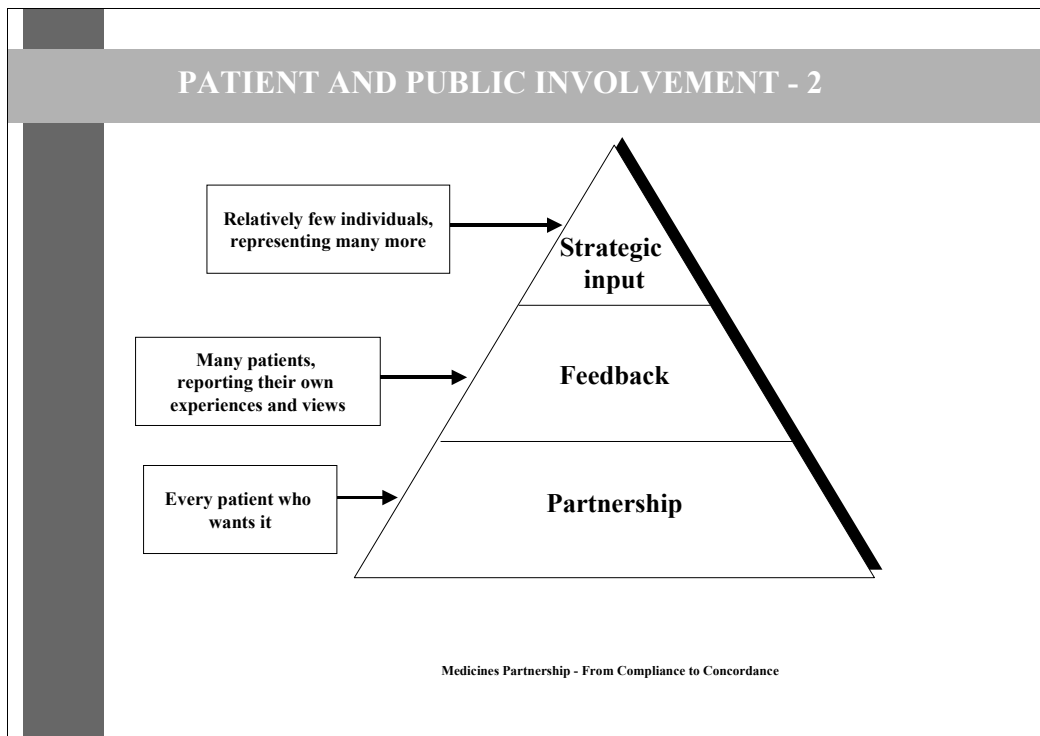


Figure 4.8 gives examples of different policies which are intended to involve patients and the public in the NHS. [See Chapter 1 for definitions and activities of Patient Forums, National Service Frameworks, NSFs and Primary Care Trusts, PCTs.]

Figure 4.8

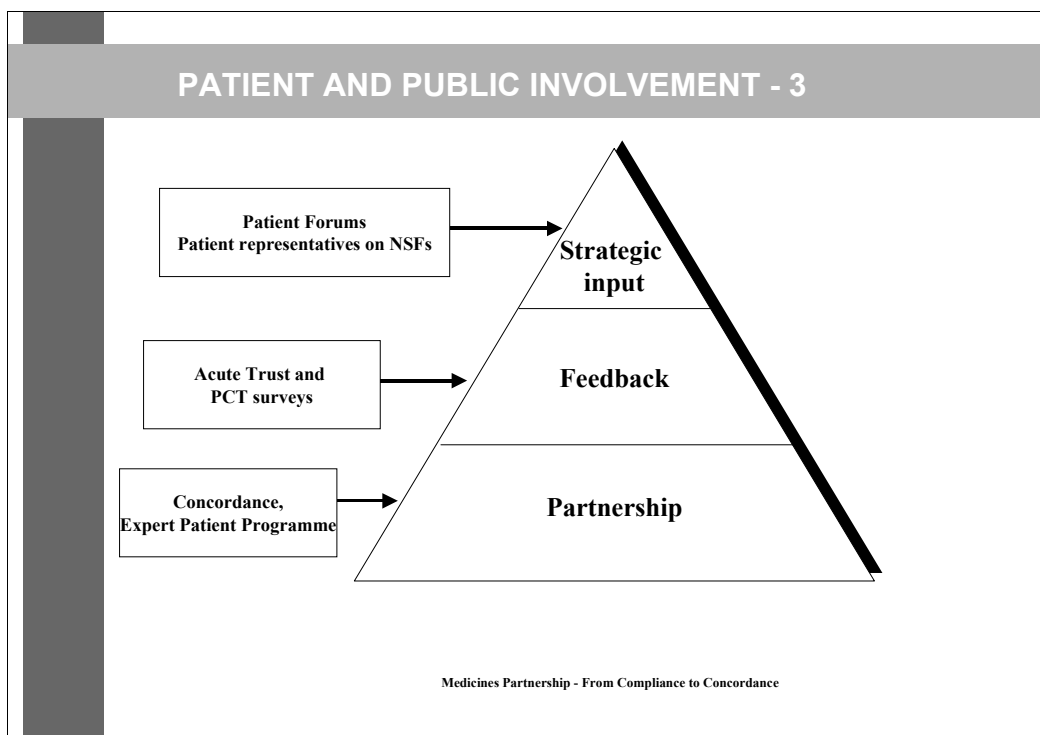
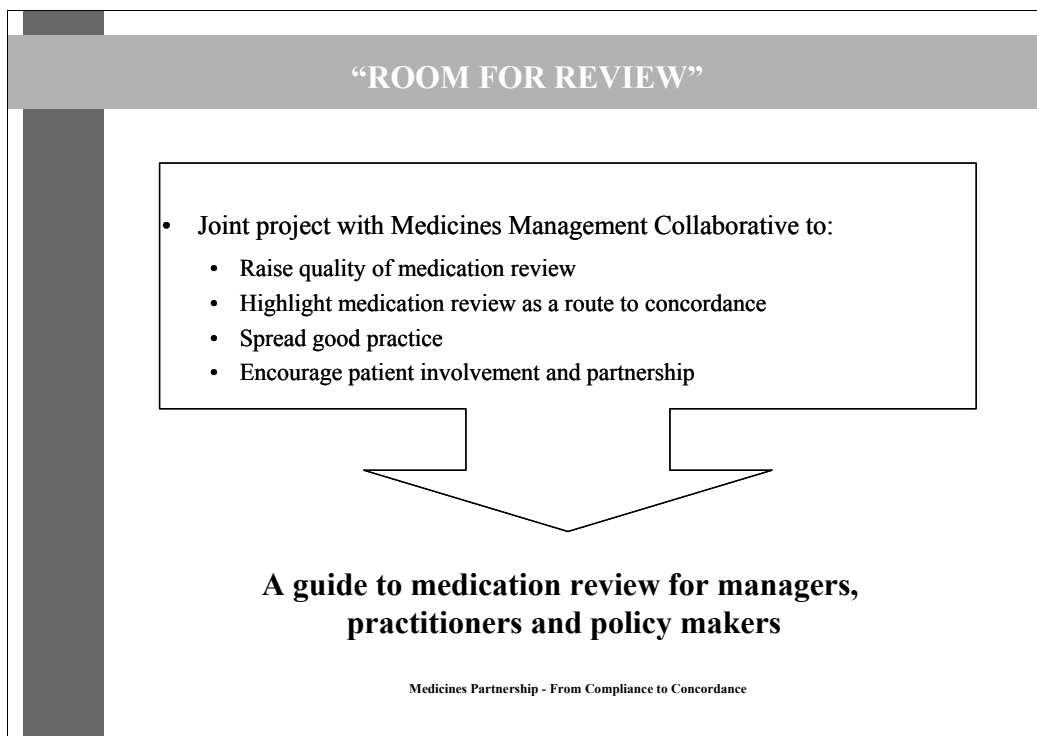


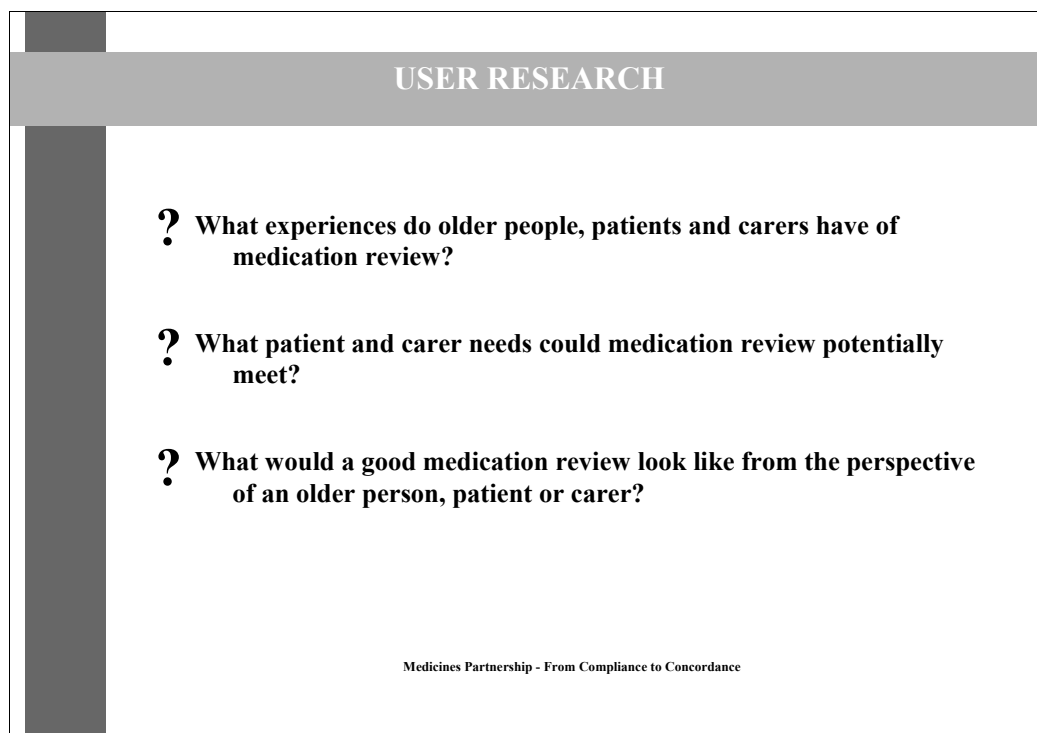
Figure 4.9



### An example from the NHS

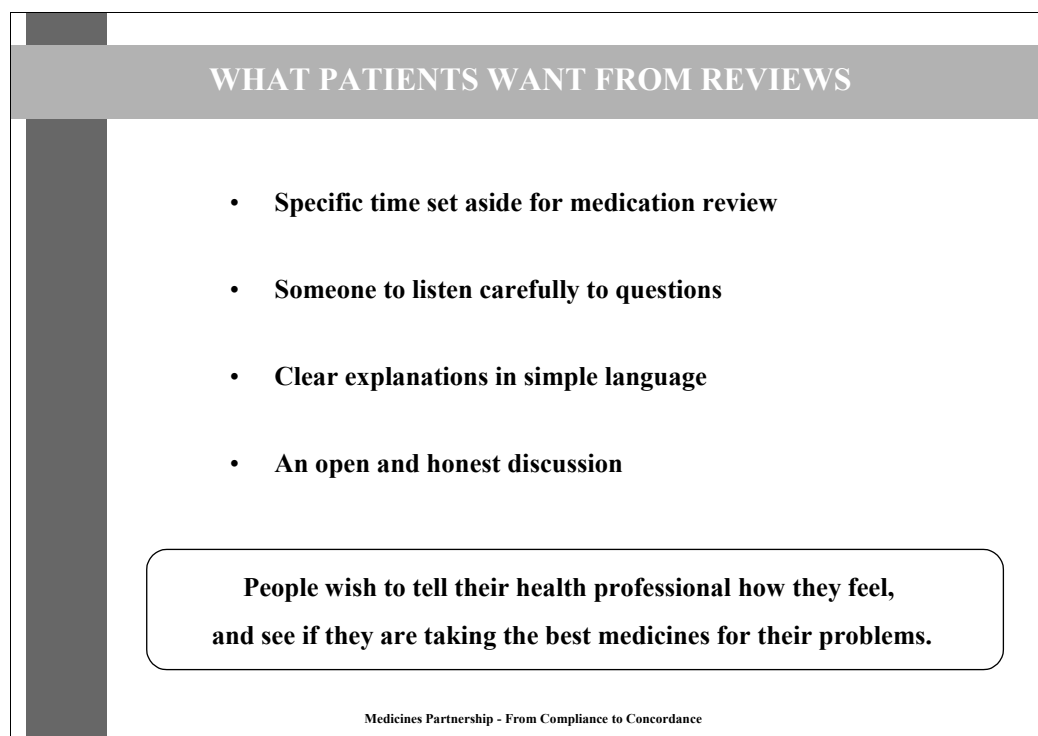
Figure 4.9 gives an example of a project with which the Medicines Partnership is involved. Under the Older People National Service Framework (launched by the government to set standards in health and social care for elderly people), every person over the age of 75 is entitled to a medications review once a year.

Figure 4.10



However, the Framework did not spell out how this should be done. The Medicines Partnership is providing guidance to health professionals on how to undertake reviews, following a piece of research that aimed to obtain feedback from older people about their specific needs in such reviews.

**Figure 4.11**



As Figure 4.11 illustrates, older people want time to discuss medication issues. All too aware of the time pressures of the healthcare system, many older people would not feel able to ask questions about their medications—unless time was allocated to the matter. Older patients also wanted someone to listen to them, who could put explanations simply so that they could understand what was being said. Perhaps the most interesting finding of all was that older people wanted an honest discussion. They preferred to be told about the side-effects of medicines they were taking and they wanted to be able to be honest about their own views about medicines. Ms Shaw noted that answers did not vary much according to socio-economic background.

Figures 4.12 and 4.13 show in more detail some of the issues that older patients would like to see included in medication reviews. According to the feedback received, patients wanted a full explanation about the drugs they were receiving, and why they were receiving them. If patients were on a cocktail of medicines, they wished to know the purpose of treatment for each of the drugs they were taking. And aside from information on side-effects, they wanted to know what their expectations of treatment might be on a day-to-day basis.

As well as the above concerns, older people also listed a number of factors they felt they needed help with when taking medicines, including how to administer the pills they were taking. As Figure 4.13 points out, older people wanted to know if new and better treatments had become available since they had first been prescribed their drugs. The quote in Figure 4.13 is from a patient with severe arthritis concerned with quality of life.

Figure 4.12

Figure 4.12 is a slide titled "INFORMATION NEEDS (1)". It contains two main bullet points. The first is "General information about the medical condition and treatment", which includes four sub-points: "Confirmation of 'what you are on and why'", "What medication is for which condition", "Likelihood of side effects actually happening to me", and "What to expect on a day-to-day basis". The second main bullet point is "How to take pills properly", which includes five sub-points: "What to take", "How much to take", "When to take it (time of day, with meals etc)", "How long from starting the treatment until it takes effect", and "Advice on 'pill pots' (i.e. MDS)". At the bottom of the slide, it says "Medicines Partnership - From Compliance to Concordance".

**INFORMATION NEEDS (1)**

- **General information about the medical condition and treatment**
  - Confirmation of “what you are on and why”
  - What medication is for which condition
  - Likelihood of side effects actually happening to me
  - What to expect on a day-to-day basis
- **How to take pills properly**
  - What to take
  - How much to take
  - When to take it (time of day, with meals etc)
  - How long from starting the treatment until it takes effect
  - Advice on “pill pots” (i.e. MDS)

Medicines Partnership - From Compliance to Concordance

Figure 4.13

Figure 4.13 is a slide titled "INFORMATION NEEDS (2)". It contains two main bullet points. The first is "Medication options", which includes two sub-points: "Has any new product come onto the market since the medication was initially prescribed?" and "Information and reassurance about 'post code prescribing': is anything being withheld for financial reasons?". The second main bullet point is "Personal beliefs and preferences", which includes one sub-point: "I should make it clear that I might be willing to shorten my life if it improved my quality of life. Doctors should be honest. They should talk about what it would mean to me and how I live my life ... If you are in so much pain that you cannot move it would not be apparent to the doctor in his little kingdom." At the bottom of the slide, it says "Medicines Partnership - From Compliance to Concordance".

**INFORMATION NEEDS (2)**

- **Medication options**
  - Has any new product come onto the market since the medication was initially prescribed?
  - Information and reassurance about “post code prescribing”: is anything being withheld for financial reasons?
- **Personal beliefs and preferences**
  - *“I should make it clear that I might be willing to shorten my life if it improved my quality of life. Doctors should be honest. They should talk about what it would mean to me and how I live my life ... If you are in so much pain that you cannot move it would not be apparent to the doctor in his little kingdom.”*

Medicines Partnership - From Compliance to Concordance

**Figure 4.14**

**INFORMATION NEEDS (3)**

- **Concerns about medication**
  - **Is a particular symptom a side effect of my medicine? Which one?**
  - **Packaging issues**
  - **Changes of medication name and/or appearance of packaging**
  - **Can pills “build up in the system”?**

Medicines Partnership - From Compliance to Concordance

Figure 4.14 illustrates some of the questions that patients may have about their medications, but are not sure how they should be answered. Ms Shaw concluded by saying that many information sources on medicines will always exist. They will be of varying quality, even if the EU legislates that patients should be supplied with more information on their prescription drugs by pharmaceutical companies. And it is the role of the NHS to develop tools and services to help patients navigate their ways through those many channels of information.

**Figure 4.15**

**THOUGHTS ABOUT MEDICINES INFORMATION**

**There should be easy access to unbiased, user-friendly information about medicines, as and when people need it**

**There will always be multiple channels and information sources of varying quality**

**Patients need help to find information that meets their needs and make sense of it**

**The role of the NHS should increasingly develop from information producer to navigator, interpreter and educator: this will require a major cultural shift**

Medicines Partnership - From Compliance to Concordance

In October 2003, the Medicines Partnership plans to launch an *Ask About Medicines Week*, hopefully involving patient groups, the pharmaceutical industry and others. The initiative will encourage patients to ask questions about their medicines. Through various media channels, patients will be guided in the types of questions they could ask and resources will be provided to answer queries.

## **Questions and answers**

### **Ask About Medicines Week**

Pharmaceutical industry representatives at the Forum asked how they should engage in *Ask About Medicines Week*. For example, what activities would be acceptable and whose information would be communicated? A patient group representative made the point that the *Ask About Medicines Week* initiative should emphasise the right of patients to information, rather than the right of pharmaceutical companies to give out information of their choosing. Ms Shaw responded that the initiative would provide an opportunity for industry to work alongside patient groups to communicate reliable and ethical information. She acknowledged that this would probably require a qualified steering group. She added that Medicines Partnership did not intend to provide all the information itself.

### **Social and cultural aspects of patient information**

One participant asked about the extent to which cultural and religious aspects were being taken into account when thinking about the provision of prescription drug information to patients—given that most publicly-available healthcare data is oriented towards white, middle-class patients. This attendee noted that 54 languages are spoken at Newnham Hospital in London. A patient group representative made the point that many patients feel ashamed if they do not understand the information they are being given. Ms Shaw stated that some good examples of projects aimed at improving health information to ethnic minorities in the UK are already in existence. On the question of understanding, she cited Australian research which showed that ordinary people have a low level of understanding of the meaning of various common medical terms.

### **Moving towards partnership**

Ms Shaw was asked how easy it would be, in practice, to move from the old-style compliance model of healthcare to one of partnership. She answered that improvements in healthcare will not be achieved until doctor-patient partnerships are achieved. The involvement of patients in treatment, she said, is a prerequisite for patient involvement in other aspects of the healthcare system. There was very little point, she insisted, in members of the public being included on the boards of PCTs, and involved in the running of the NHS, if their views are ignored whenever they visit their GP.

## Chapter 5

# The way forward

*The discussion period at the end of the High-Level Forum was chaired by Stephen McMahon, chairman of the Irish Patients' Association, and member, Expert Advisory Group on Media and Health, The Council of Europe. From this latter discussion (and throughout the day), three themes emerged. The first theme focussed on patient rights to information; the second on the role that pharmaceutical companies should play in delivering that information. The final theme concerned the need for patients and patients groups to act more cohesively to allow their voice to be better heard. PatientView looks at these themes and considers possible next steps.*

### **The High-Level Forum meeting**

On November 5th 2002, PatientView and the International Association of Patients' Organizations (IAPO) held a High-Level Forum meeting in the Boardroom of *The Economist*, in London. The Forum was the venue for the launch of the PatientView/IAPO report on improving public access to, and the quality of, prescription drug information in the UK. The event was sponsored by Merck Sharp and Dohme Ltd.

The Forum examined events surrounding the European Parliamentary vote of October 23rd 2002 on the European Commission's proposals to reform European legislation on

### **Stephen McMahon** *[chairperson]*

**Chairman, Irish Patients' Association,  
and member, Expert Advisory Group on Media and Health, Council of Europe**

Mr McMahon co-founded the Irish Patients' Association (IPA) with his wife in 1995. He had been aware that many people could not successfully interact with healthcare systems. The association was formed in response to this need, to listen to patients, place them at the centre of healthcare systems, and to give them a voice in how care should be delivered—whether on a local, regional or national basis.

Mr McMahon is the IPA's nominee to a number of important advisory groups, including: the Enterprise Liability Advisory Group to the Department of Health and Children; Health Service Quality Assurance Group, set up under the Programme for Prosperity and Fairness; A&E Forum; National Steering Committee on Primary Care—*A New Direction*. On a local basis, he is the IPA's nominee to key policy groups dealing with: Complaints and Informed Consent; "Non-Punitive Reporting of Medication Errors"; and the Medical Council's Advisory Group on Competence Assurance. Mr McMahon also sits on the Council of Europe's Expert Advisory Group dealing with Media and Health. Mr McMahon has contributed articles to the medical media, has given lectures to undergraduate and postgraduate medical schools, and has made numerous presentations at local, national and international conferences.

Mr McMahon was educated at Blackrock College and Trinity College Dublin, where he obtained a Diploma in Advanced Systems Analysis. He worked for a leading multinational oil company for 30 years. During his assignments as an analyst and manager, he gained wide business experience covering Marketing, Business Analysis, Procurement, and Operations (where he was coordinator and implementation advisor of global best practices on a local basis). He currently works as a business consultant. He is married with two children.

pharmaceutical products (specifically, the amendment to the Advertising Directive). This amendment would have allowed pharmaceutical companies to supply European consumers with more “communication” about prescription medicines in three disease areas [see Introduction]. The Forum gave participants the opportunity to discuss future strategies on publicly-available prescription drug information.

Attending the November 5th meeting were senior executives from a number of disease-specific and umbrella patient organisations, as well as MPs and peers, officials from the UK Department of Health, elected officers from the medical profession and pharmacological and nursing communities, members of the media, and representatives from the drug, healthcare consultancy and insurance industries.

Although the Forum attendees were mostly a British-based group, participants also came from Ireland, the Netherlands and Italy. Some of the patient group representatives sat on the boards of a number of important European bodies, including IAPO. Forum participants were affiliated to the Advisory Committee of International Experts of the European Health Forum Gastein, the European Health Policy Forum (DG Sanco), the Expert Advisory Group on Media and Health at the Council of Europe, the European Federation of Crohn’s and Ulcerative Colitis, and the scientific committee of the European School of Oncology. The diversity among the attendees meant that the Forum assumed both a UK and an international dimension.

Discussion at the Forum centred around three major themes:

- the rights of patients to be informed about their treatments;
- the role of the pharmaceutical industry in supplying product information; and
- the need for various patient-led and national government-led initiatives to ensure that the patient voice is given a fair hearing.

### **The rights of patients to information on prescription drugs**

Consumer groups have argued that the present abundance of information on general healthcare matters undermines the case for the liberalisation of laws to permit the release of more publicly-available data on prescription drugs. Yet despite the presence of a mass of general healthcare information, accurate facts about prescription drugs are scant. The UK and Sweden have perhaps the most liberal and progressive attitudes toward the dissemination of product information. But UK patients continue to rely largely on doctors and patient groups for prescription drug information [as the PatientView/IAPO UK survey showed; see Chapter 3].

Participants at the High-Level Forum recognised that the pharmaceutical industry holds prescription drug information useful to European patients, but to which patients currently do not have access. Such information would help patients make treatment choices and manage medication. Attendees widely agreed that well-informed patients make better progress with treatment. An example was given at the Forum: the worldwide drop in mortality from diabetes during the 1970s and 1980s can be mainly attributed to the introduction of self-medication, which had the effect of creating better-informed patients with more responsibility for their own health.

### **Current sources of prescription drug information are inadequate**

According to the PatientView/IAPO UK study, UK patient groups believed that the biggest current gap in prescription drug information centred around the benefits of treatment. Governments across Europe prevent pharmaceutical companies from communicating the benefits of their products to patients, fearing that any such practice might encourage drug usage. Even within the somewhat more liberal environment of the UK, NHS Direct Online (the UK government-funded Internet site dedicated to providing the public with healthcare information and advice) offers little data on many commonly-prescribed medicines, let alone the benefits of specific treatments.

Internet sites are potentially able to communicate considerable amounts of prescription drug data to the public. In fact, one of the most well-known sources of publicly-available data on prescription medicines at the moment are US-based Internet sites. Unfortunately, US Internet sites have two disadvantages for European patients. Firstly, the Internet is a relatively socially-exclusive medium, primarily accessed by patients in higher socio-economic groups. Secondly, US sites are geared toward an American audience. European patients need to speak English to gain any benefit from US sites. Perhaps even more importantly, the indications for which US drugs are approved can be surprisingly different from those of drugs approved in Europe. An interesting example of this element of the transatlantic divide was cited in the Forum presentation of Kathy Redmond of the European School of Oncology. The US Food and Drug Administration (FDA), Ms Redmond observed, has approved AstraZeneca's cancer drug Nolvadex for the prevention of breast cancer. In Europe, however, the drug is available for treatment purposes only [see Chapter 2].

### **Healthcare inequities and patient consent**

The Forum emphasised that the need for better information on prescription medicines is urgent, both in the UK and elsewhere. Forum participants spoke of two major reasons for the urgency. The first major reason is that without better prescription drug information, patients are being denied their fundamental right of equal access to treatment. Equality of access is certainly absent in the UK. Local budgetary deficiencies mean that patients in some parts of the country may not be given drugs readily supplied to patients in other areas of the UK. Even when cost considerations are not applicable, the differing skills and personalities of GPs can produce inequities. Not all medical professionals are equipped with the latest data on medical treatment or are willing to share that treatment information with patients—even when patients demand it. These two points probably explain why the PatientView/IAPO EU-wide survey found that only half of the UK patient group respondents said that patients “highly trusted” the prescription drug information supplied to them by their doctors.

The second major factor underpinning the urgency of the need for better prescription drug information is the necessity for patients to be able to make informed choices when consenting to treatment. According to Stephen McMahon of the Irish Patients' Association, an unwritten (and very traditional) contract with doctors asks that patients effectively consent to the treatment prescribed them by their appointed physician. Consent requires delivery of all the information that will enable patients to make an informed choice—including information on prescription drugs. Patients, if they are ever to become consenting partners in their treatment, have a right to, and need, information on prescription drugs.

### **The attitudes of other groups**

The Forum noted that patient groups and consumer groups hold polarised views on the subject of prescription drug information. Consumer groups believe that supplying prescription drug information to the public would lead inexorably towards fully-fledged US-style direct-to-consumer advertising. Consumer groups and payers of healthcare services assert that such information would also accelerate patient demand for medicines, and thereby threaten national healthcare budgets. Patient groups think differently. The majority of participants at the Forum felt that European patients have the right to be informed about their treatments. MEPs acknowledged that right—for the first time—on October 23rd 2002 [see Introduction]. The views of the MEPs, however, have yet to be endorsed by EU member states in the Council of Ministers.

### **What next?**

Participants at the Forum recognised that much could be done, within the current legislative framework, to improve product information for patients. Kathy Redmond pointed out, for example, that the leaflets that drug manufacturers provided inside the packaging of medicines could be simplified, making them understandable to larger numbers of patients. And many other delegates spoke of a need for more nationally-based online and written information on medicines. Only Sweden, it was mentioned, possesses a formulary of approved medicines that is both officially endorsed and available to the public. But at the end of the Forum, participants recognised that perhaps the biggest challenge for European patients was getting the various different interested parties to recognise that patients have the right to all manner of prescription drug information.

### **The role of pharmaceutical companies as information providers**

The second theme regularly touched upon throughout the day's proceedings was the actual and potential relationship between pharmaceutical companies and patients. Stephen McMahon noted that patients, industry, government, the media and others should contemplate gathering together to formulate a strategy on prescription drug information. Such a move would in itself be a massive step forward. Mr McMahon also observed, that whatever strategy emerged from this grouping, it should be centred around the patient. The process, he added, had to be ethical and accountable, and any recommendations made should do patients no harm.

Many of the patient groups attending the Forum believed that patients should be given the right to seek prescription drug information from pharmaceutical companies without impediment. Few of the groups, however, felt that the pharmaceutical companies themselves should be given free rein to supply prescription drug information to the public. This latter point was perhaps best expressed by one of the participants from a UK-based patient group:

*"I am very comfortable with the suggestion that every patient should have the right to approach pharmaceutical companies for information on their products. I am less comfortable with the notion that pharmaceutical companies should have the right to pass product information to patients."*

The meeting, however, also recognised that if the latter opinion was held to be the norm, difficult questions could arise. The Forum heard of valid instances in which patients (or even the general public) should be provided with prescription drug information, even if the information is unrequested. One of the examples mentioned concerned patients taking anti-hypertensive drugs. Many of the products in this category of medicine are decades old, but continue to be prescribed. Although new and better medicines have long been available, patients themselves can remain ignorant of the fact. Another example given was diabetes. In Europe, large numbers of diabetics remain untreated. Prescription drug information from these two disease areas (and others) might act in an empowering fashion, allowing patients to come forward and approach their GPs for initial or improved forms of treatment.

The problem is communication: how to get useful and appropriate information to the individual in need of it. In part, the issue comes back to education, and how to empower patients to find information and access it. Joanne Shaw of the Medicines Partnership provided an example from her own organisation's work to suggest how pharmaceutical companies might be able to act as valuable partners in initiatives aimed at encouraging patients to think more about their medication. Medicines Partnership, she said, plans a nationwide project, *Ask Medicines Week* [see Chapter 4]. The project will supply information brought together by representatives from across the healthcare sector, including drug companies. Medicines Partnership will act as gatekeeper to the information. Such a partnership with pharmaceutical companies may only be plausible within the current legislative framework if information supplied by industry stops short of being product specific.

The Forum attendees admitted the difficulty of ensuring that the most passive members of the patient population could be made aware of important facts capable of affecting their healthcare outlook for the better. The patients groups attending the Forum, however, shied away from endorsing prescription-drug television campaigns for the masses. Participants felt that educational television campaigns might result in some vulnerable patients approaching their doctors for unnecessary medication.

### **The patient voice**

The third of the overarching themes to arise out of the Forum concerned the volume and potency of the patient voice. To date, national patient groups have felt disenfranchised from the manoeuvres made by the European Commission and European Parliament on the subject of prescription drug information for the public. Patient access to prescription drug information has consequently been given a low policy priority among national patient organisations. But, given the fact that the 15 member states will in due course be called upon to provide their view on the European Parliamentary vote, Forum attendees thought that nationally-based patient organisations should be doing more to project a governmental-level voice on the matter of prescription drug information.

The following proposals were made at the Forum as to how patient groups could increase their influence upon government:

- Patient forums should be created in each of the member states, to lobby respective countries on the issue of prescription drug information.
- More partnerships between patient organisations and the healthcare structures

currently in place (such as the medical profession) should be promoted, to effect change. In the UK, patient groups should familiarise themselves in particular with the new bodies and structures that the Department of Health has set up to push for greater patient involvement.

- More independent data should be produced supporting the views of patients on the subject of the supply of prescription drug information (such as the PatientView/IAPO survey). Sound economic arguments regarding the cost effectiveness of medicinal treatments should be developed, too.
- The debate on prescription drug information should be de-polarised, so that patient groups can make an effort to forge a new alliance with the consumer advocacy sector (with which patient groups share many common goals).
- The public's awareness of patients' rights to prescription drug information should be raised.

### **The way forward**

The November 5th 2002 PatientView/IAPO High-Level Forum was one of the rare occasions in which a single country's patient groups (covering a wide span of disease areas) came together with representatives from industry, government, the media, and the medical profession and academia to discuss such a politically high-profile subject. According to Stephen McMahon, chairman of the Irish Patients' Association, and member of the Council of Europe's Expert Advisory Group on Media and Health, for that reason alone, the Forum should be regarded as a success:

*"The November 5th 2002 High-Level Forum meeting set a course of action in which patient groups can be united by a common purpose, with common needs within Europe. We patient groups can connect as real partners with our national governments and with European regulators—to influence the decision-making process, and to have these reasonable needs and wants met."*

Apart from the achievement that bringing together such a diverse group of people in the healthcare sector represented, the meeting was considered a success due to the breadth of the discussion that took place on the subject of publicly-available prescription drug information.

### **The need for further discussions**

Not surprisingly, lack of time prevented many aspects of the debate from being aired in depth at the PatientView/IAPO Forum. One element missing from the Forum's conclusions was a true agreement among attendees on the distinction between advertising and information—despite the presence of broad agreement that such a split could be made. Although participants at the meeting seemed clear among themselves about the differences between disease and product information, the characteristics that separated prescription drug information from prescription drug advertising remained blurred. The Forum heard that if definitions of these two terms are not discussed, the process of freeing-up the supply of prescription drug information to patients and the public could unfortunately be delayed.

Another subject not covered was the legal liability of providers of prescription drug information. One attendee, however, did observe that pharmaceutical companies' own in-

house legal departments can make the companies as cautious about the type of prescription drug information they provide as any externally-appointed policing agency.

The subject of healthcare financing and reform was also not fully discussed at the Forum. This topic is important given the fact that one of the main arguments against pharmaceutical companies supplying prescription drug information to the public is the belief that such data might ruin national healthcare budgets and cripple healthcare systems. A participant did suggest that the issue of healthcare financing was a matter for central and local government, and separate from patients' rights. Nevertheless, a need exists to examine the economic impact of better-informed patients on healthcare and social security systems, and also to consider whether budgetary considerations are a valid reason for governments to restrict the supply of patient information.

Finally, perhaps not everybody attending the Forum at first appreciated the speed with which attempts to recast the present legislative framework on prescription drug information are moving in Europe. By the end of the meeting, though, most delegates were open to advice on the dangers of not acting quickly.

#### **Enlarging the debate: interactive television**

If large bodies of the patient population are to gain access to more and better prescription drug information, novel communication channels need to be opened up. The European Commission has suggested that the Internet will be a vital portal of communication. At the Forum, Joanne Sawicki of Channel Health TV described how interactive digital television was able to draw in elements of the patient population that would not normally make use of the Internet—notably, the lower socio-economic classes [see below]. She emphasised that interactive digital healthcare broadcasters could process complex healthcare data into small chunks of text readily absorbed by viewers.

#### **Enlarging the debate: advertising**

The debate on November 5th followed the agenda set by the European Commission and centred on prescription drug information, not on prescription drug advertising. Areas included the sorts of information that should be supplied to patients, the amount of information, and the necessary controls. Advertising as a subject was only touched upon obliquely, during a moment when definitions of the distinction between information and advertising were being briefly explored.

However, nobody at the Forum considered the consequences of denying patients prescription drug information, even when it is in the form of an advertisement. Had such a view been taken, the belief in the difference between advertising and information might not have remained so pronounced. Free markets, after all, tolerate advertising. The medium provides information and increases transparency. Problems only occur when advertising becomes biased or unbalanced. Pre-vetting or self-regulation of advertising could prevent these difficulties from occurring. When the subject of prescription drug information for the public is next aired in a similar venue, perhaps it is worth considering effective methods of policing both publicly-available information on prescription medicines and publicly-available advertising of prescription medicines in tandem—asking whether the same rules could be applied to each, regardless of the purpose of the content of the message, might produce an interesting debate.

## **Conclusion**

Patient groups have been forced to react to proposals from the European Commission and to criticisms from consumer organisations. To date, these latter groups have set the agenda for discussions on supplying the public with prescription drug information. But the subject is more complex and far broader than current debate would have us believe. Patients and patient groups alike are now being presented with an opportunity to express their opinions on this important subject. The time is nigh to take the lead, rather than merely follow discussions. The only hurdle is the current fragmentation of the patient advocacy movement in Europe. Hopefully, more country-based forums, like that of November 5th 2002, will provide the means for patient groups to work together to set their own agenda, instead of having others do it for them.

## **Improving the quality of general healthcare information**

British patients are overloaded with general healthcare information. Data comes from all sources: friends and family; other patients; doctors; nurses; pharmacists; patient package leaflets (PPL); other leaflets left in clinical settings and pharmacies; the media; the Internet (home and foreign websites); national and local government; and cable health channels. More recently, a few television campaigns have focused on certain high-profile conditions, seeking to raise patient awareness of the causes, symptoms and dangers of each of the diseases concerned. Call centres funded by drug companies have proliferated. In rare cases (such as hormone therapy), and on specialist recommendation, drug company representatives have even talked directly to patients, advising them on how to administer their drugs.

The November 5th High-Level Forum presentations and the ensuing discussions [see Chapters 2 to 5] made clear that much of the vast amount of healthcare information currently in the public domain is of poor quality, unregulated, inappropriate and prejudiced. The Forum also observed that patients have to work hard at finding information relevant to their own specific conditions.

Forum participants proposed three different overarching strategies to improve the access of UK patients to presently-available healthcare information. These strategies, which also aimed to improve the quality of the information, were as follows:

- reorganisation of the information into a more coherent format;
- the accreditation and vetting of information with patient involvement; and
- the education of the public in healthcare matters.

Forum attendees described a number of ongoing projects which have tried to make healthcare information more user-friendly. The projects (some of which were welcomed by the audience, others were not) covered the following subject areas:

- **Simplification of data**

The new Community public health strategy is intended to make information about healthcare systems more transparent. The European Health Policy Forum (DG Sanco), an information and consultation mechanism involving stakeholders in the health field, is a step in this direction. It aims to ensure that the European Commission's health strategy is transparent and respondent to public concerns. DG Sanco is considering sieving through some of the mass of healthcare information presently available in Europe, to impose some structural order upon that data. [For more details, see <http://forum.europa.eu.int/Public/irc/sanco/Home/main?index.>]

Some commentators argue that the concept of such a centralised approach seems impractical, given of the speed of medical innovation and the rapid changes that can take place in treatment guidelines (particularly, for instance, in HIV/AIDS therapy).

- **Building on current healthcare information systems**  
The UK National Electronic Library for Health already exists and can be built upon.
- **Disseminating information at local level**  
The European Commission has funded numerous projects by pharmacy/patient support groups. The projects help explain treatments, offer regular consultations with pharmacists (on subjects such as asthma medication), or give advice on self-medication.
- **Utilising the media more effectively**  
Joanne Sawicki, founder and former chief executive of Channel Health TV, described an NHS-funded project in which her company provided information to 2m viewers across the UK on all aspects of pregnancy and birth. The project, which was 18 months in the making, collated all the best-practice information on the subject compiled by the Department of Health. Channel Health then independently created a television series featuring the lives of seven women attending the same GP practice. Included in the series was an interactive feature with 1,500 pages of text (the content of which ranged from detailed medical information to simple advice along the lines of “Don’t forget, Dad”). The interactive facility was primarily accessed by viewers in the lower socio-economic groups.

Delegates’ attention was drawn to the existence of numerous agencies charged with the responsibility for vetting and accrediting healthcare information. In the UK, for example, the Centre for Health Information Quality (C-H-i-Q) was established in 1997 by the NHS Executive to act as a clearing house on all aspects of patient information. The best-known such agency at global level is the Geneva-based Internet Healthcare Coalition, which provides accreditation to global Internet sites. But the High-Level Forum heard that although some of these vetting organisations have patients or patient groups as advisors, they do not always represent the patient perspective. Commonly mentioned at the Forum was the suggestion that patient groups themselves should play a far more important role in policing healthcare information.

### **Better patient education**

In addition to the need to improve the quality of, and access to, publicly-available healthcare information, the Forum stressed the importance of improving the general education of the public on medicines and health—a practice which takes low priority in the schools of most countries. A recent study conducted in Australia showed that an understanding of relatively uncomplicated medical terms (such as analgesic and decongestant) was low among the general public. Hence, education about health—preferably starting at an early stage—should also be given priority alongside information strategies.

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