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Consumers and Health Information: Is knowledge really power?

Panel:

Peter Pitts, Center for Medicines in the Public Interest
Colin Webb, Vice-President, European Patients' Forum
James Copping, European Commission, High-Level Pharmaceutical Forum

Chair: Gunnar Hökmark, MEP (EPP, Sweden)

Introduction

Gunnar Hökmark:

Thank you for the opportunity to chair this event on a very important subject; you have taken quite a risk. There is a paradox here: one part of the society which is the most modern and dynamic, academic and future-oriented, is also the most regulated of all. If we need to reminisce about what the planned economy was about, we may look at the health care sector. And if one sector in society should be subject to central planning, I don't think health care or pharmaceuticals is the one.

Take automobiles: all those who lived in the planned economies know what their cars looked like and how long it took to get one. But it would still be preferable to have those results for automobiles than to have them in health care! An important aspect of patient information and pharmaceuticals is that there are thrilling perspectives in this area.

Peter Pitts:

Healthcare in the 21st century is a tale of two cities. The first city, the healthcare city upon a hill, provides miracles on a daily basis. We are living longer, healthier lives due in large measure to the miracles of biopharmaceuticals. If disease is the enemy, then medication is our secret weapon. The sister city is the city of fear – fear of diminishing access, adverse events, the unknown, and most importantly, fear of responsibility.

Samuel Johnson said “the future is purchased by the present.” Let's use that as our point of departure.

Consumers have become a driving force in the healthcare industry, demanding choice and access, spending cash out-of-pocket on self-care services, and making healthcare the number-one topic

searched on the Internet. Patients, not physicians are the fastest growing readership segment of the major medical journals.

Knowledge is power, but it is also a responsibility. Drugs have benefits, but they also have risks. In short, we do not live in a perfect world and things are rarely ever 100 percent. And that's frightening to a lot of people here and in the US when it comes to the miracles of modern medicine.

According to recent polls, people are more distrustful of the pharma industry than in the past. Why is that? Is it because more people are taking more medications? Is it because of drug safety issues such as the Vioxx recall and the lack of transparency of clinical trials? Is it because of the price/value debate?

The answer is, "yes, but ..." Yes, but those are manifestations of larger problems – and those problems are confusion, frustration, and fear. According to Juvenal, "All wish to possess knowledge, but few, comparatively speaking, are willing to pay the price."

Welcome to 21st century healthcare and the empowered consumer. Today, the "learned intermediary" fears being replaced by the mass marketer, the patient is increasingly the purchaser (often a reluctant one), and physicians are becoming vendors. Managed care directs, "serious and life-threatening" diseases have morphed from polio and diphtheria to cancer, AIDS and Alzheimer's Disease. And global regulatory agencies are under fire for bringing drugs to market *too swiftly*. How times change. There really shouldn't be any wonder why people are frightened. The entire healthcare paradigm has changed.

Woody Allen said that "Change is inevitable – except from vending machines." Management guru W. Edwards Deming said that "Change is not required. Survival is not mandatory."

Change is frightening. In the 21st century, we must all be *pharmaceuti*. Today, pharma companies are viewed as being in the business of making money rather than in the enterprise of discovery and development of life-saving therapies. Can savvy industry marketers help recapture the high ground by positioning the industry as made up of scientists rather than salesmen? As preceptors rather than promoters?

A good place to start would be to rethink consumer communications programs, both direct-to-patient advertising and those with the broader goal of educating the industry's various constituencies (ranging from patients to doctors, academics to legislators, policy wonks to pundits), on the role the industry plays in areas other than sales and marketing. The good news is that there's a lot to say.

Educating the health consumer

A recent consumer survey in Europe asked people in Great Britain, the Czech Republic, France, Germany, Italy, the Netherlands, Spain and Sweden what reforms would most likely increase their quality of care. In every nation, by a large margin, they answered "giving patients more information about their illness." Health care education is the consumer's Rosetta Stone, and public

policy institutes, pharmaceutical firms, health care professionals, disease organizations and patient advocates, *along* with government must be allied and aligned conduits.

When it comes to consumer education, there are four hard questions, (1) **what** should be said, (2) **to whom** should it be said, (3) **how** should it be said, and (4) **who is responsible** for spreading the gospel of good health.

The “**what**” part is uncomfortably difficult since many insurers and providers don’t want their customers to know about safe and effective medicines because they don’t want to pay for them. The “**to whom**” part is easy – health messages must be communicated broadly to consumers. The “**how**” part is more complicated.

Rudyard Kipling said, “Words are the most powerful drug used by mankind.”

This is particularly true when it comes to the issue of health care information to patients, because if government and industry doesn’t know *what* can be said or *how* it can be said – then the public health is not being optimally served.

Europe has the opportunity to learn from America’s mistakes. And there are a lot of them. Today you have the opportunity to devise a system – you *must* design a system wherein direct-to-patient information is designed in equal parts as savvy marketing strategy and powerful public health tool – because these are not mutually exclusive concepts. That being said, it’s imperative to understand and accept that we are living in a post-Vioxx world where direct-to-patient information can no longer exclusively mean direct-to-consumer advertising (DTCA). Today it must mean DTCC – direct-to-consumer communications, or “DTC squared”.

US: reforms, research and regulations

Let me spend a few minutes sharing with you the current environment in the US, so you can learn from our experiences – and our miscues.

Reforms in US direct-to-patient communications are being driven by the winds of the perfect storm – the nascent presidential election cycle, the emergence of drug importation as a populist political issue, Medicare Modernization, and drug safety. A grand slam of highly charged issues that made it not only possible, but also predictable that the media and, as night follows day, politicians would begin portraying Big Pharma as the new Big Tobacco.

And direct-to-consumer communications, in the US most commonly meaning direct-to-consumer advertising, being as it is the most public face of the industry, found itself squarely in the bull’s-eye of pundit satire and political outrage. It was into this arena that trade organization PhRMA launched their voluntary Guiding Principles for direct-to-consumer advertising. And this document needed to be more than a transitory inoculation against the enemies of the industry. It needed to make a difference.

Winston Churchill said, “Americans always try to do the right thing – after they have tried everything else.” If the pharmaceutical industry wants to change its image on Capitol Hill and in homes nationwide then it's time for Big Pharma to turn from pyrrhic victories to long-term strategies. In this respect, the new DTC guiding principles, even though voluntary, are a very important step in the right direction.

More on those new guiding principles shortly, but first some history – because those who do not learn from history are bound to repeat it.

In September 2003, I was Associate Commissioner at the Food and Drug Administration and served as a panelist at a two-day public hearing on pharmaceutical direct-to-consumer advertising. Three months ago, no longer a senior government official, I testified in front of my former colleagues on the same subject. But what I heard was more important. According to research presented by academics from such places as Harvard Medical School and the Mayo Clinic and from consumer advocates such as the National Consumers League, pharmaceutical direct-to-consumer advertising is, indeed, advancing America's health – most specifically by getting more people to visit their doctors.

That shouldn't be a surprise to anyone in this room or to anyone who's taken Marketing 101. Why? Because open and honest communication legitimizes. More specifically, it helps to de-stigmatize certain diseases and encourages people to talk with their doctors about problems previously considered taboo – like depression. Other research demonstrated little or no correlation between a brand's DTC spending and its cost. In other words, brands that spend more heavily on DTC advertising do not necessarily cost more than their less-advertised competition.

According to research conducted by the Food and Drug Administration, between 3-5% of all doctor visits in the US are scheduled specifically because a patient (otherwise known as a “person”) saw a pharmaceutical advertisement. Now, we can debate whether or not 3-5% is a lot or a little, but I think we can all agree that it's a significant number.

Effects of advertising

So, let's delve a little more deeply into advertising-driven office visits. According to FDA research, of patients who visited their doctors because of an ad they saw, and who asked about that prescription drug by brand name, 87% actually had the condition the drug treats. But has the public health been served? Has it advanced America's health? The answer is a qualified “yes.”

According to the same FDA study, slightly less than half of doctors said that DTC-generated visits resulted in better discussions and made the patient more aware of treatments. And in 6% of those advertising-generated visits, a previously undiagnosed condition was discovered. Why is that so important? Because earlier detection combined with appropriate treatment means that more people will live longer, healthier, more productive lives without having to confront riskier, more costly medical interventions later on.

Only 7% of doctors said they felt “very pressured” to prescribe” a particular advertised drug.

When the FDA panel probed into the question of “pressure to prescribe,” what we found out was that the real pressure was *time* pressure. More patients are coming in armed with more questions.

Do physicians feel that direct-to-consumer advertising advances the public health? It depends.

According to the FDA study, a majority of doctors feel that pharmaceutical advertising increases patient awareness and involvement, improves compliance, and enhances the overall doctor-patient relationship.

But – and it’s a big “but,” only 40% said that DTC advertising has affected their patients and their practice either “very” or “somewhat” positively. Another 32% of the doctors surveyed believe that DTC ads have a “somewhat” or “very” negative impact. And the remaining 28% said it had no impact at all.

40% positive. 32% negative. 28% neutral. Room for improvement? Absolutely.

Are patients informed?

So, how can pharmaceutical direct-to-patient advertising be made to be a better public health instrument? Let’s further investigate the problem so we can find the solution.

According to FDA’s own study, 65% of doctors feel that the DTC ads their patients see confuse them about the relative risks and benefits of prescription drugs.

That’s a problem. It’s a big problem. It is, in fact, THE big problem. In the agency’s 1999 study, **56%** of people who saw a pharmaceutical magazine ad said that they read the brief summary “not at all” or “a little.” (And I think it’s a fair assumption that those who replied “a little” were being polite.)

In the 2002 study that number jumped to **73%** – a 17 point increase. During that same three-year span, those saying they read “Almost all” or “All” fell from 26% to 16%. Not decimal dust by any stretch of the imagination. In the decimal dust category consider this – in 1999 3% said they weren’t aware that there *even was* a brief summary. In 2002, this figure dropped a full decimal place to 0.3%. In other words, more people know the brief summary is there, and fewer people are reading it. And that’s reflective of how people’s attitudes towards DTC ads have changed during those same three years – for the worse.

In 1999, 70% of patients surveyed agreed either “strongly” or “somewhat” to this statement: *“Advertisements for prescription drugs give enough information for me to decide whether I should discuss the drug with my doctor.”* In 2002 that number fell to 58%. Not trivial.

If information is power (and it is), then pharmaceutical advertising is not as empowering as it once was. Why is that? The answer is embarrassingly obvious. Risk information is hidden in plain view and benefits are communicated broadly. It’s not a question of fault. It’s a question of fact. Risk

information is neither designed nor delivered to be user-friendly. At present it is designed (if you can even call it “designed”) to be “*in compliance*.”

So, how can DTC advertising change for the better?

Improving communications

When it comes to direct-to-patient communications, be it product advertising or disease awareness, the best and most expeditious way to get there is to apply sound *social* science to better communicating *medical* science.

Claude Debussy said, “Music is between the notes,” and this is as true for follow-on biologics as it is for communications oversight. But the same techniques used to judge clinical trials cannot be applied to communications. Current information-to-patients policy, both in the US and Europe, is not based on a scientific analysis of the target subject – the consumer. And this raises a crucial question – where are the social science metrics, indeed the rules, driving government oversight of pharmaceutical information to patients?

As FDA’s Associate Commissioner, I toured the US speaking with advocacy groups, physicians, consumers, pharmaceutical firms, and communications professionals on how pharmaceutical communications could be made better. Specifically, how patient information could be constructed to more clearly and meaningfully communicate the risk/benefit equation of advertised drugs and raise the public’s awareness of crucial health issues such as diabetes, hypertension, and high cholesterol.

What I heard time and again was that the US government needed a solid benchmark study to serve as a foundation for sound policy decisions; a social-scientific protocol, a quantitative research project composed of structured, closed-ended questions and a sample size representative of the U.S. population with regard to geography, race, gender, age, and the treatment/disease of interest. A study armed with questions that would provide insight into the most effective ways to communicate risks in ways that are understood by the reader. A study that would provide a social science-based regulatory framework, potential templates, metrics and, most importantly, add predictability to the government’s review process. Today this process is underway – albeit slowly, in the US. Europe should consider a similar study, because as any doctor on either side of the Atlantic will tell you, prescribing a solution without a proper diagnostic process is malpractice.

Reaffirm, redeploy and rethink

Today there is a new pharmaceutical Theory of Relativity: $R^3 = DTC^2$. Now, in order for you to understand the elegant physics, allow me to reveal to you the three “Rs” of pharmaceutical direct-to-consumer communications.

The three “Rs” are derived from PhRMA’s 15 “Guiding Principles,” and the first “R” is “**Reaffirm.**” Eleven of the fifteen principles fall into this category. In essence they say that pharmaceutical companies will follow the rules and guidances set forth by the FDA – and that every single new ad will be submitted for review.

The second “R” is “**Redeploy.**” Guiding Principle #10 calls for the *de facto* banishment of reminder ads (which mention the product name, but not what the product does) resulting in the need to redeploy the dollars and tactics previously handled by these obnoxious little billboards.

Other little things that will need to be redeployed, according to Guiding Principle #13, are television ads that discuss lasting erections and satisfying experiences. Now they’re limited to “adult viewing hours.” Only in America would this be considered an “advance.”

The third, final, and most important “R” is “**Rethink.**” And it is here that the rubber really meets the road. This is the hard **R**. The **R** that challenges the conventional wisdom of the pharmaceutical marketing mind. The **R** that demands a redefinition of long-term thinking from the end of the quarter to the end of the quarter-century.

Consider the third PhRMA Guiding Principle, *“DTC television and print advertising which is designed to market a prescription drug should also be designed to responsibly educate the consumer about the medicine and, where appropriate, the condition for which it may be prescribed.”* Also #14, *“Companies are encouraged to promote health and disease awareness as part of their DTC advertising.”*

This is the operative phrase, “promote health and disease awareness”.

While the passive voice wording of these principles makes the overall effect more, well, passive – the main thrust of principles 3 and 14 are clear – less undisguised selling and more on-purpose education. It’s an important first step in the campaign to reposition the industry from being assailed as salesmen to a more preferred position as scientists, to move from hucksters to healthcare heroes.

There will have to be a shift to longer-term strategies, because “educating” about a disease means accepting the mantle of teacher. The teacher becomes the expert and the expert gets the business – but not in the same truncated time frame that hard-sell advertising produces.

“Promoting health and disease awareness” also means a fundamental shift in the marketing mix. Advertising is a wonderful brand builder but it’s not nearly as potent a brain builder.

Which brings me back to direct-to-consumer communications, DTC². Direct-to-consumer communications means selling the brand as well stimulating the brain. It means new strategies and tactics. And it means that the time is forever gone when a pharmaceutical CEO can speak about “responsible promotion” while turning a blind eye to the actual tactics being used on the air and in the doctor's office to meet aggressive quotas and keep the Street happy.

DTC² isn’t just about selling. It’s about saving lives and saving our health care system. It’s about improving disease awareness and defeating patient non-compliance – estimated to cost the US

health care system billions of dollars a year in increased emergency room visits, unnecessary surgeries, expensive hospital stays, and lost productivity.

Understandable and accessible information that employs leveraged learning strategies and incorporates both brain as well as branded messages will also help address the global crisis of embarrassingly low health literacy.

Successful DTC² requires a **reaffirmation of responsibility**, a **redeployment and reassessment of resources**, and the toughest R of all, the ability and willingness to **rethink** the roles of the many tools in the pharmaceutical marketing armamentarium. $R^3 = DTC^2$.

And that's as true in Europe as it is in America So whether the discussion is about advertising, or information, or communication, let's all heed the words of former Canadian Prime Minister Pierre Trudeau who advised "Let us overthrow the totems, break the taboos. Or better yet, let us consider them cancelled. Coldly, let us be intelligent."

Thank you.

Colin Webb:

As announced in the program, I'm vice-president of the European Patients' Forum, but I'd like to start by explaining how I got there. I happen to be an international HIV-AIDS activist; I'm HIVpositive. When I was diagnosed in 1992, I was given seven or eight months to live. I'm also a retired Special Forces colonel, so I have a strange background. But I'm used to managing information.

The effort to free up information was really started years ago by HIV activists who demanded knowledge about treatment options literally in order to survive! Personally, I became involved six years ago, and the issue was access to information. And we got the information because of who we are, but most people couldn't. We are in this ludicrous situation in Europe, where anyone is free to give information, quite legally, about pharmaceutical products, except the industry which makes them. The other problem is that, unlike the United States, we are a collection of different states and there is no harmonization.

Pressure was building in various ways; then all of a sudden, the Commission comes up with an idea: a three-disease pilot program for HIV-AIDS, asthma and diabetes. Which makes you wonder: where did this come from? And I must admit I still don't know and I'm not sure there is a straight answer. Privately, I was told that these three were selected because the patients were making the most trouble. Then there were meetings in Parliament, and we were all very concerned. To be quite honest, I was against it in the beginning. People would come to me and say: "You're lucky Colin, you've got HIV!" But there was also another faction which really wanted to clamp down on information. Why? Some of them were politically motivated, and went as far as saying that there shouldn't really be a pharmaceutical industry. Quite amazing when you know that the Soviet Union is dead, because it didn't work.

The tragedy is that it was voted down in Parliament, maybe because the basic text was French and upon translation into English, the word “information” changed into “advertising”. Which opened the can of worms and set the politicians running for cover. But it was not entirely dead, because the Commission was tasked with finding a mechanism, and today a working group has been created for information to patients.

The working group has around 30 members and its objective is to find a mechanism to bring information to patients. There is one patient representative: me. We had a first meeting in January 2006, and our second meeting today. But the worst thing is that there was no parliamentary representation whatsoever for the first meeting (although there was one today). It looks now as if the ball has finally started rolling, but we will need to steer it in the right direction. The fear is that some organization will come stamping all over it with the term “DTC advertising” which would kill the initiative stone dead. We should stick to information to patients and we are expanding the patient representation to subgroups within the next six months.

The whole of Europe is watching us and expect something to come out of this, so we have got to move things forward. Doubtless, we have people against us, mainly for cost containment reasons. In the UK, dedicated wards have been closed down, because of informed patients who are involved in the whole premises. But I believe things are coming along, and I sincerely hope that we won't make the same mistakes you made in the US.

James Copping:

Many points made by Peter Pitts about DTCA are important and we can learn from those lessons. But any reference in Europe to DTC advertising in the current discussion will just lead to a lot of noise without any constructive debate. As both Peter and Colin said, the focus has to be on communication. The key issue is to think about how we can go forward. Europe is a patchwork of nations with different cultures, languages, health care systems and also different expectations.

Medicines are heavily regulated, and if we really want to establish a single European market in pharmaceuticals to help industry and the patients alike, we need to find a sensible balance in regulation. The Commission believes it has done its share by the recent pharmaceutical law, but we have to find a balance between the national and community levels of competence. This will make life challenging to us within the working group on patient information.

To revert briefly to DTC advertising, it is clear from recent debates in Parliament and the Council of Ministers, that Europe has said no to DTCA and yes to providing better information. But that is how far we have gotten; when it comes to how to achieve this, we go off in different directions.

There are some equations: the member states have all the power in terms of patient information, but often not the resources needed. One key constituency – the industry – conversely has the resources, but not the power to engage. From the Commission's perspective, there has to be a balance which

allows us to put resources, skills and knowledge to good use, without threatening the states' responsibility for health care and control of health systems and pharmaceutical budgets.

We have to change the climate of debate which soured badly during the discussion of the three therapeutic pilot studies. Part of the background to the patient information working group was to tackle this and produce a productive working environment.

So, what are we doing? We are faced with a system where patients, other than the information obtained from health care professionals (doctors, pharmacists, nurses), have access to information once they have bought their medicines. The information provided in the patient leaflet is comprehensive, but many studies have shown that this either is not read, or if it is read, it is not understood. We want to change this situation to make more information available before the patients get anywhere near the medicines. But the current legal framework heavily restricts what we may do with the official information. There have been changes made to the structure of the leaflet, and there will be new guidelines on readability, and most importantly that the leaflet should be used and tested to give the proper feedback on how it is being read.

The European Medicines Agency in London is on the forefront of this, developing the European Public Assessment Reports which will give more information to patients, specifically on why a given medicine received a license. These are beginning to come in, some are already available on the website for some newly authorized medicines and will be expanded to other centrally authorized medicines. There is also the famous database (for which there is yet no name), which will eventually hold statutory information for all authorized medicines in Europe (leaflet, label, summary of characteristics, assessment report). The first part of the database will be available to the public in late 2006, hopefully in September.

Secondly, and this is very important, the Commission is working on the report to the Parliament and the Council on ways to improve the environment for patient information in Europe. This will focus on the existing legislation and will make recommendations for changes. So there is a prospect of long term, fundamental changes but it will not be an easy task, as there will be significant debate in the Parliament and the Council.

Another area which complicates the environment for patient information, is that there is on one hand the heavily regulated statutory information, and on the other general information which is largely unregulated on the EU level. There are many good resources out there on product and disease information (such as national databases and websites) but nothing yet on the European level. This forms the background for developing the working group on patient information which was set up under the Pharmaceutical Forum. It is designed to be a high-level group, looking at the issues affecting the competitiveness of the European pharmaceutical industry in line with public health objectives. Its membership will be at ministerial level for member states, there will be representatives from industry, patients, health care professionals, health insurance groups and the European Parliament. The Forum will meet for the first time in September 2006, and there are three working groups to support it: information to patients, pricing and cost-effectiveness of medicines.

Within the patient information working group which met today, we have looked at a number of areas, in particular non-statutory information where there is more flexibility, the types of

information we can provide, how it is delivered and the areas where it can be accessed. This goes back to the “what, whom and how” issues which Peter Pitts raised.

We will produce a report to the Pharmaceutical Forum, but the work will go beyond that to find practical solutions to be implemented at the European level to produce sustainable change in patient information. In parallel to the working group, a new health portal will be launched in May. It is a website providing access to authorized national websites throughout Europe on all aspects of health information. Secondly, there is separate work on the development of quality criteria and seals for websites.

From the Commission’s point of view, we want a system where patients can be empowered to take an equal part in health care decisions. To do that, they need more information and we all want to make high-quality information available as soon as possible. We believe that all stakeholders have a role to play to provide this information, but the tricky issue for us is to find the appropriate framework which national regulatory authorities can live with.

Debate:

Peter Pitts:

Somebody asked whether a more informed patient uses medicine more appropriately. The answer is: yes, of course. The lie to get past is that we take too many medicines. When, in the US, there are tens of millions of undiagnosed diabetics and hypertensives, we aren’t taking too many medicines! When doctors are saying that they are not prescribing medicines to get patients out of their office, we are not taking too many medications. A dangerous patient is one who self-prescribes or orders drugs on the internet, without a doctor’s intervention. Ignorance combined with access is dangerous. Education combined with access is a potent step forward for public health.

Colin Webb:

I met a very senior member of government, a secretary of state, on this issue. But the meeting was not really on this, but concerned trade just before the Cancun WTO conference. And I asked for her take on information to patients. She replied that, whether you like it or not, it’s going to drive up costs of prescription drugs. I said “what about those of us who pay for our health care?” And she really didn’t have any answer to that.

James Copping:

One of the obstacles is regulations. We have an unsustainable mix of regulations, focused very heavily on the statutory information, and the legislation on advertising was largely drafted in the 1980s, before the Internet became a daily feature of many people’s lives. This needs to be addressed in the review.

The pharmaceutical industry has a lot to contribute because of the resources, skills and expertise and we have seen in the working group that the industry plays a constructive part. It's amazing to me that an industry which plays such an important part of our health care is often seen on par with the tobacco or the oil industry. It's not clear to me why this is the case, but we need to develop good working relationships between all of us. We all agree that we need good quality information, but none of us can do it alone.

Kajsa Wilhelmsson (Health Consumer Powerhouse):

Today, you cannot single out pharmaceuticals within a treatment which combines provider, device and medicine inputs as equal factors. The Commission has recognized this and a new directive tries to sort out what is a device and what is medicine. I was wondering whether the quality seals for websites would also concern pharmaceuticals? I see a need for one regulation for all kinds of health information, taking into account that there are many spammers promoting products which should not be promoted. In Sweden, a woman died of breast cancer because she had read somewhere that if you undergo surgery for breast cancer, it will spread! And you cannot get to the people providing this kind of information, because they are not a pharmaceutical company.

Also, vaccines are excluded from the Directive: when I talked to the Swedish government about vaccines, they said "we don't regulate vaccines, because it's too complicated". Should there not be one single law on health information, rather than one specifically for pharmaceuticals?

Eline van den Broek (European Independent Institute):

In the Netherlands, we recently introduced a trademark for information websites which should help in identifying reliable sources of information. Is the Commission considering such a solution?

Peter Pitts:

In the US, we found that you cannot regulate health care communications for different diseases and devices with one single directive or law; it doesn't work. It worked really well until medicine got sophisticated; today, you no longer have devices, but technology: drugs which combine devices and therapeutics, dietary supplements and qualified health claims. There are tremendous grey zones between different types of health care communications. Part of the learning from the US experience is that different types of communication must be regulated differently.

Colin Webb:

I think the idea of trademarks is good; but the interesting thing is that in the debacle of pilot studies, the Commission suggested something similar. And all those in favour of freeing up information thought it was a great idea. But it was killed.

James Copping:

The quality seal was part of the initiative from colleagues in the Commission dealing with the information society for websites generally, and not specifically for pharmaceutical sites; but there is no reason why it shouldn't be applied across the board.

In terms of health care information, the problem is that currently you can develop all sorts of information, but as soon as you make references to a particular medicinal product, this is subject to the legislation governing medicine (advertising ban). Although the Commission doesn't need incentives to come up with new regulations, trying to regulate health care information would be a nightmare. Often, local and regional levels are best and will always produce better outcomes. The question for Europe is how we may help to improve the quality of information and support local communities.

But we should not separate medicines from broader health care issues, and one of the tasks of the working group is to develop basic information about diseases and products where broad treatment options are discussed, without falling foul of the law. And pharmaceuticals are often one treatment option. Regulating poor information on websites just will not be possible, because of the nature of the internet; but what you can do is to help people identify good quality information.

Peter Pitts:

As a former regulator, I think rhetoric is important; and rather than discussing how to regulate information, we should talk about opening up access to information, rather than restricting it.

Shelagh Kerr (Phrma):

Has there been any progress in making the distinction between information and advertising? In the first round, some member states considered any mention of a brand name or company as advertising, whereas others considered traditional advertising, e.g. on television. This would help clarify the issue.

Question:

The health care professionals also need to be empowered and taken into account; also patients will need in the long term to know where information about them comes from. Basic records should be available to the patient.

Eline van den Broek (European Independent Institute):

The big topic in the Netherlands right now is that the pharmaceutical industry is advertising to doctors, but labeling it updating of new drugs, etc. Isn't the media a big factor in the mixup of advertising and information?

Gunnar Hökmark:

I'd like to add the following: how does the restriction of information to patients affect the development of products for the industry? If Ericsson and Nokia were not allowed to advertise to consumers, it would certainly influence the way these companies behave and develop. In the EU-US perspective, this may be a difference in competitive edge for knowledge companies.

Question:

In the UK, doctors say that patients are increasingly demanding specific products and refusing generic substitutes. They therefore must consider the budget and not only the medical perspective. How does this tie in with providing patient information, since doctors will in many cases recommend equivalent treatments and not necessarily the one requested?

Peter Pitts:

Research in the US also shows this: patients come in and ask for a specific drug by name, and sometimes doctors have to argue as the patient doesn't want to take the drug as recommended. If the patient wants a brand name drug because it is more effective, paying out of pocket, it becomes a personal financial issue. Are doctors having to play the role of spreadsheet accountant? Yes, they are: welcome to 21st century health care.

When you don't have a robust program of informed consumers, and medicines for high blood pressure for instance are numerous ("me-too" drugs; one is supposedly as good as the other), I want to know about the drug which will help me. This is the information most governments will withhold, because they don't want to open up formularies or expand cost, even if this ultimately improves health care.

Medical journals have papers on drugs paid for by pharmaceutical companies. It's not against the law to write a paper discussing a pharmaceutical product, but it is illegal to have a marketing program do the same; this is confusing. It's a philosophical loophole.

Colin Webb:

In the old days, you were told to listen to the doctor because he knows best; and generally, doctors were trying to do a good job. When it became more complicated – especially in my case, where there are all sorts of combinations to be taken – doctors realized that agreement with the patient was essential. This is one reason. The other is hard nosed cost; then came the compensation culture, and doctors started getting sued. I feel sorry for the GPs because they are under huge budgetary pressure.

On the distinction between information and advertising, this is a push/pull thing, although this may seem oversimplified. If somebody asks for information about a product, to me this is information. If somebody sends me mail through the door, that's advertising. But we are not going down that route anyway.

The entire argument is really not whether information should be given to the wider public; generally people agree to this. The question is: who is going to be the gatekeeper?

James Copping:

Part of the problem of course is that information and advertising are not mutually exclusive; legislation cannot decide it, although it has to play a role. Luckily, our working group can proceed without getting bogged down in this.

Should health care professionals get better information? Absolutely, but this is outside the remit of our work. I know that the EMEA is looking into how to give them access to the database at the appropriate level, and to patients alike.

Concerning the media, I think the experience in the UK and elsewhere with health scare stories and product withdrawal shows that this can easily explode into complete misunderstandings, especially in a very competitive media environment as in the UK. But there is also a poor understanding of the risk/benefit argument: what does safety mean in the context of medicines? I'm not sure if newspapers are good at putting this across.

On competitiveness: medicine is not like other products. We want to see a competitive environment, but we cannot treat medicines as we treat cars or shoes. The big competitive issue in Europe is more about the fragmented nature of what is supposed to be a single European market. There are many things which should be on the hit-list (such as research funding), rather than the issue of advertising.

