

Health
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**ENSURING
INDEPENDENT
MEDICINES
INFORMATION
IN EUROPE**

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SEMINAR REPORT

Ensuring independent medicines information in Europe

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Preface

Today, European consumers are overwhelmed with health information. But, how much of it is actually useful and developed with their needs in mind? Much of the information currently circulating is incomplete, biased or simply wrong. As societies become more interconnected and technologically advanced, sharing information across borders has become a common phenomenon. Yet, serious efforts to check the quality of this information or restrict its distribution are limited by many factors. While there are numerous examples of balanced, unbiased, and complete information about medicines and health in Europe, these initiatives remain hard to find.

Europe needs a health care policy that encompasses unbiased and comparative information about medicines that can be accessed by all citizens.

Recent debates in Europe, prompted by the Commission's Pharmaceutical Forum initiative, have placed the issue of medicine information high on the agenda. However, civil society has been forced to play a minor role in this discussion, in part because of the nature of the process, which discourages broad participation and dissent.

This meeting is being held in an attempt to remedy this situation. Such an important subject deserves serious debate and diverse viewpoints so that we can all gain a clearer picture of the current situation and the problems that need to be addressed.

HAI is actively engaged in the European discussions on information to consumers. We will continue to promote policies that help people to use medicines wisely and offer a complete, unbiased picture of treatment options (including non-drug solutions).

The next few months will be critical as the European Commission prepares its report on this issue, setting the stage for the next step in this high-stakes debate. HAI urges all stakeholders to get involved in this crucial debate and join us in promoting people-centred health policies that will empower consumers and promote public health, instead of commercial agendas.

Teresa Alves

HAI Europe Coordinator

Welcome address

Dr. Tim Reed, Director, Health Action International, Global Office, Amsterdam

Why is it important to come together and review and debate some of the problems surrounding the issue of drug information? Medicine information is an important issue today because it remains a debated point within the European Union. It is also one of the topics at the core of HAI's own work.

In 2003, when policymakers strongly rejected the idea of allowing European drug advertising to consumers, there remained a caveat. The European Council instructed the Commission to revisit the subject of patient information in the future. Brussels is gladly doing that now using a new group called the Pharmaceutical Forum.

Europeans are drifting into a world of non-independent information. And be sure that what is decided in Europe will have implications far beyond its own borders—in areas that are already struggling under the burden of poor information. It is impossible to talk about patient information in Europe in isolation. It is part of a larger debate, part of the rational use of medicines. It is important to remember that the decisions made in Europe on information and the use of medicines will have global ramifications. Will they promote health or will they advance another agenda?

This meeting's topic has brought together a diverse group. It includes consumers, patients, politicians, regulators, representatives from insurance funds, the medical profession and the pharmaceutical industry. Today's speakers will present differing views and that promises some lively debate.

Thank you for coming.

You say information, I say advertising

Barbara Mintzes, Assistant Professor, Department of Anesthesiology, Pharmacology and Therapeutics, University of British Columbia, Canada and Teresa Alves, HAI Europe Coordinator, Amsterdam

In 2002, the European Commission proposed a pilot project to allow direct-to-consumer advertising (DTCA) in Europe for asthma, diabetes and AIDS drugs. These were exceptions to the standing EU ban on this kind of advertising. Months later, the proposal was overwhelmingly rejected by the European Parliament by a vote of 494-42. It was rejected again by the EU Council in 2003.

While the legislative changes were under discussion, DG Enterprise insisted that such exceptions would not be DTCA. Rather, it argued, they would be part of an effort to make information more readily available to patients suffering from common chronic illnesses. However, documents released by the EU openly floated the idea of abandoning restrictions on the advertising of medicines.

At present, EU legislation (Article 88 (a)) (of Directive 2001/83/EC as amended by Directive 2004/24/EC and Directive 2004/27/EC) prohibits the advertising of prescription drugs to the public. At the same time, Article 86 (2) allows information on diseases to be given to the public as long as there is no direct or indirect reference made to a specific product.

The work of the forum

Now in 2007, the central player in the information/advertising debate is the EU's Pharmaceutical Forum, a new body created by the Commission to address public health issues and pharmaceutical policy. (The Forum has been described as a successor to the earlier G10 Group which examined ways to make Europe's pharmaceutical sector more competitive globally.) It is chaired jointly by the Commissioners of DG Health and Consumer Policy (Sanco) and DG Enterprise and Industry and has a large representation from industry.

The Forum has a number of working groups including one on information to patients. This sub-group has drafted an information package on diabetes for the public. However, consumer groups, health professionals and insurers have criticised the draft because of the weakness of its methodology. In particular, for the lack of comparative drug information and information about the quantified harms or benefits of the drug.

In addition, the quality of the criteria formulated by the working group was considered inferior to existing published standards for consumer health information. They also failed to address conflicts of interest or bias in information made available to the public.

In April of this year, the Commission issued a report based on a Parliamentary request regarding drug information to the public. The report stated that attention should focus on the availability and quality of information and not on its source. It acknowledged industry as an important source of drug information for patients but said it could not fulfil its role in this area because current legislation prevented it from distributing such information.

The thrust of this report makes one wonder if this is a repeat of what happened back in 2002. The report doesn't mention DTCA once, yet it is the foundation on which it is clearly based.

Expanding the borders of information

At the same time that the Commission's Pharmaceutical Forum is compiling patient information with an obviously industry-influenced agenda, there are additional examples of industry influence in patient compliance programmes, websites, and advertorials. Less subtle advertising has also been planned, for example, a group of pharmaceutical companies were preparing to start a new television channel on disease conditions.

Most of these efforts fall under the category of "disease mongering". That is, they aim to expand disease definitions in order to increase drug sales. Some material is full of inaccuracies about disease prevalence, risks, and potential treatment benefits. Many fail to comply with WHO's Ethical Criteria standards on drug promotion. And, unfortunately, the regulatory response to them has been inadequate.

EU regulations do not prohibit giving information to consumers. In fact, Article 86 (2) allows such information, as long as there is no specific product information mentioned. Industry is not excluded from giving consumers information, but it is forbidden to advertise specific medicines to them.

We know from experience in other countries that such advertising can stimulate inappropriate use of new medicines (a small proportion of all medicines on the market) before their risks or benefits are fully known. This can lead to real public health problems, which was demonstrated with unfortunate consequences in the case of the arthritis drug, Vioxx® (rofecoxib).

Vioxx® and advertising

Between 1999 and 2004, a whopping US\$500 million was spent on advertising this drug in the United States. This was despite the fact that trials showed a four to five times increased risk of heart attack among patients using it. Studies also showed that it was no more effective than other anti-inflammatory drugs for arthritis. However, before this information became more widely known and accepted, and the drug was taken off the U.S. market, an estimated 88,000-140,000 extra heart attacks had occurred, 40% of them fatal.

It is said that DTCA can create more informed, empowered patients, but the example of Vioxx® reveals how important health information that posed a threat to sales was kept from the public.

Conclusion

It is crucial that public health and welfare are the top priorities when talking about information. The public needs unbiased, accurate, comparative information on the pros and cons of all treatment choices, including the option not to be treated. These messages should not be buried in advertising. Article 88 must remain intact and enforced.

It is clear that industry wants a larger role in the area of drug information and it could play a larger role by improving the quality of product information, packaging and patient information leaflets. If they want to contribute more to informing the public about their medicines, companies should fully disclose all pre- and post- marketing drug effectiveness and safety studies.

Morning discussion

Main points from members of the audience:

The cost of advertising- Advertising based on the U.S. model would bankrupt national health services in Europe. The demand for drugs is led by the people who are promoting them.

Low health literacy- If industry wants to give important drug information to consumers, the highest priority for information provision is the 30-40% of people living in Europe who have low health literacy.

Barbara Mintzes mentioned a study that looked at whether basic education criteria formed the basis of informed treatment choice, including health literacy ideas. That is, how do you decide if a drug is good for you? Almost all of this type of information is missing from printed drug advertising targeting the public and the study did not examine 30-second TV commercials. She considers claims that advertising is a good information source to be inconsistent with reality.

Ethical criteria standards- The WHO's Ethical Criteria state that advertising should not take "undue advantage" of people's concern for their health. However, how does one determine "undue advantage"? Especially in light of the fact that most medicine users are quite vulnerable because of illnesses or conditions that might make them more eager to seek treatment.

Barbara Mintzes responded that the criteria can be subjectively interpreted but it can lead to fear mongering, increased prevalence rates, or making a disease/condition sound more afflicting than it is.

Non-drug options- Another participant suggested that if industry wanted to give full information it also had to include non-drug treatment options that might positively affect health outcomes. For example, by adding exercise to a person's daily routine, instead of telling them to take a medicine to help reduce weight.

Barbara responded that it was not in the industry's interest to tell people about cycling or other forms of exercise that could be used instead of drug treatment. She said the pharmaceutical industry is biased toward increasing medicine sales because it is beholden to shareholders.

Teresa Alves added that in the draft package on diabetes information, the influence of lifestyle and diet on health did not receive the same attention as medical treatment. This was clearly an effort to misdirect attention. The whole package is geared towards the seeking of treatment for type 2 diabetes.

Afternoon session

Differing perspectives:

Introduction by the Chair- Didier Rod, medical doctor and former member of the European Parliament (MEP)

The best informed patients are medical doctors. They read papers and books, take courses, and receive information from insurance companies and regulatory authorities. However, very often, due to a lack of time, they rely on another big source of information—pharmaceutical industry representatives. This is despite the fact that doctors know their information is not always complete. It is important for doctors to have independent sources of information.

Patients also clearly need and want drug and health information. However, it is sometimes difficult to understand this information. Patients want information that tells the truth about side effects and efficacy. Today, European consumers get their information from medical doctors, pharmacists, newspapers, TV, radio, books, health services and the Internet. Often they cannot be sure of the accuracy of the information. It can also be difficult to distinguish between advertising and information.

As a former MEP, Rod tried to promote the interests of patients and doctors. He wanted to enable them to get the maximum amount of high-quality, independent information possible. This is why it was so important for the 2002 directive to talk about making things more transparent and getting information to the people. This is also why the Parliament rejected the DTCA directive by a large majority. It is also the reason why he is surprised that four years later the discussion about the possibility of allowing the industry to give information to consumers has to be revisited.

The real question is not about getting information from the industry to patients. It is part of the discussion on controlling the kind of information the industry gives to doctors, to authorities, and the problem of determining what is independent, reviewed information for patients. This meeting's broad panel should help lead a comprehensive debate on these issues. The hope is that this will help everyone, especially the Commission, to understand the points of view expressed by patients and doctors.

Patient information in Europe:

The Pharmaceutical Forum as one of the drivers for change?

Christian Siebert, Head of Unit, Competitiveness of Pharmaceuticals Unit, European Commission's DG Enterprise and Industry

The European Commission has a number of objectives related to patients, information and access to medicines. To begin with, it believes all European patients should have equitable and quick access to the medicines they need. At the same time, the Commission wants to support investment in new medicines. It is also working to empower patients to have easier access to the quality information they need so that they can take greater control of their own health care.

The workings of the forum

To try to make these things happen, the Commission has created the Pharmaceutical Forum. The Pharmaceutical Forum's composition, working methods and discussions on patient information have to take into account the variety of interests, demands, expectations, participants and objectives represented in the group. This is extremely difficult. The Forum's greatest weakness is also its strength: the large variety and diversity of interests present in this process. Moving ahead and getting some degree of consensus on things remains complicated and challenging.

The Forum has the participation of health ministers from all 27 Member States (as well as representatives from EFTA). It is chaired by Commissioners Verheugen and Kyprianou. It also includes 10 stakeholder organisations including representatives from patient groups, the pharmaceutical industry, doctors, insurers and pharmacists. It also has three MEPs as members who participate under personal title.

The Pharmaceutical Forum aims to respond to current health challenges and to strengthen industry competitiveness. It wants to initiate stronger EU cooperation on pharmaceutical policies and develop concrete proposals on the three outstanding G10 recommendations regarding information to patients, pricing and relative effectiveness. Each of these areas is now represented by a Forum working group.

Regarding information, the Forum's members want to improve the information available to patients about their medicines and related health issues within the existing legal framework. The European Union is facing an important variety in the type of health information available to consumers depending on where they live.

Working groups created

The working group on patient information hasn't precluded any type of information from being considered as valid for patients. The working group wants to explore different providers, different objectives, and the possibility of using different channels to disseminate information. This is a real challenge for maintaining quality and access. While it is true that there is not a lack of information, there remains a problem of quality and access. The most informed patients are English speakers with Internet access. At the same time, it is difficult for many consumers to judge the quality of the information they find on the Internet.

There are three pillars of work within this working group. The first focuses on non-statutory information (related to diseases). The objective here is to develop key elements for model packages of information on conditions/diseases, using diabetes as an example. The working group is also discussing quality criteria for information.

The second pillar involves statutory information (about diseases) and work was carried out in a different framework. Related objectives include a separate 'Report on current practices with regard to the provision of information to patients on medicinal products'. In fact, a consultation on the draft report took place in the spring of 2007.

The third and final pillar concerns accessibility. Its objectives include developing recommendations to enhance information provision in health care environments (particularly, in pharmacies and hospitals); identifying information tools for citizens; and providing guidance for National Competent Authorities to increase the effectiveness of health awareness campaigns.

Results to date

What has been accomplished so far? The bulk of the work relates to information on diseases, as work on medicines is outside the mandate of the Forum. One objective has been to develop key elements for model packages of information on conditions or diseases. Diabetes has been chosen as the test case. A diabetes fact sheet was drawn up, containing essential information on the condition and its various treatment options. More than 70 groups responded to the draft.

The working group has been trying to define quality criteria for information. It was decided that it would be useful to have agreed, common standards for high quality information at the EU level. Work has been done to determine core principles for information to patients on diseases and treatment options together with a methodology of use. This is to provide a “toolbox” of good practice and means to help patients evaluate health information.

The Pharmaceutical Forum has just adopted a second progress report about its work. It has now been released and contains a detailed description of how things stand and what has been achieved so far. Discussions on the Forum’s third and final year of work are now underway. Work should continue on the quality principles and more fact sheets on diseases or conditions could be developed. The Forum process will come to an end in one year.

Direct-to-consumer information

Ilaria Passarani, European Consumers’ Organisation (BEUC)

The Pharmaceutical Forum

The European Consumers’ Organisation (BEUC) expressed its concerns regarding the High Level Pharmaceutical Forum. BEUC believes that the Forum has little credibility, both in its composition and methods of working.

As to the composition of the Forum, the representatives of patient groups, the three representatives of the European Parliament—and obviously the pharmaceutical industry—are overwhelmingly on record as being in favour of amending the current provisions of the directive on the advertising of prescription medicines.

BEUC also questioned the process by which the fact sheet on diabetes was developed. This was a task that should have been given to independent experts, working as a scientific advisory committee and not to a sub-group of a working group of the Pharmaceutical Forum. The process of preparing the fact sheet was politicised by the context in which it was developed. The role of the pharmaceutical industry in the sub-group was particularly questionable, especially given the opposition of the industry to the use of the term “unbiased” as one of the quality criteria for information to patients. The industry prefers the term “objective” but objective information can be partial, incomplete and biased by omission, especially in the context of trying to provide full health information to patients and not just some information on specific medicines.

In general, the composition of the Forum and the working procedures give the pharmaceutical industry a disproportionate influence over the outcome. Because of these flaws BEUC considers that the outcome of the Pharmaceutical Forum cannot and should not form the basis for future policy in this area.

Determining patients' needs

To actively participate in their health care, consumers need more and better information about health, diseases, treatments and medicines. This information should be independent, accessible, reliable, accurate, appropriate, consistent, evidence based, unbiased, updated, comparative, transparent and understandable. Information needs are very complex and highly individual and it is essential both for policy makers and for health professionals to identify those specific needs and respond accordingly.

There is room for improvement and a need to empower consumers who are confronted with a growing amount of information. But stating that there is a "patient information syndrome" and that pharmaceutical company can solve this problem is not true: readily accessible sources, adapted to the different national or regional context are available, offering patients relevant information to make informed choices.

BEUC called on the European Commission to conduct a comprehensive study to identify and quantify patients' and consumers' need for information on medicines and health related information.

BEUC also reaffirmed its strong opposition to any amendment in the current EU legal restrictions on what pharmaceutical companies can do in relation to advertising/information to patients. Any change in the current EU law would be a conflict of interest and industry self-regulation is not the way forward. There are many ways for industry to provide high-quality information to consumers that are permitted under the current legislation. The ban is not as burdensome as industry suggests.

Incoherent policy making for medicines and health policies at EU level

At national level, pharmaceutical policies are an integral part of health policies. This is not the case at EU level, where DG ENTERPRISE, the Directorate General responsible for the competitiveness of the industry and not DG SANCO, the Directorate General responsible for public health policy, is in charge of pharmaceutical policy. As a consequence, EU priorities and policies for medicines reflect both the uncoordinated nature and inherent industrial policy leanings of the decision making structure. BEUC opposes this allocation of responsibilities as it leads to a "disconnect" between important aspects of health policy, and acts as a barrier to coherent policy making.

We believe that the fact that medicines are approached as part of industry policy means that health policy, health interests, health professionals, independent health economists and health users have less input into policy making than they should; and industrial interests more influence than they should.

BEUC therefore argues for unified health policies competences within the Commission and for more concerted action in health.

What do patients need?

Fiona McLean, European AIDS Treatment Group (EATG)

The provision of quality information to patients saves lives and improves quality of life. Information can help people live with chronic conditions. Yet, to be effective, the information must be comparative, show benefits and risks plus the consequences of accepting no treatment. Information should also be easily accessible and adapted to local culture. Efforts made to inform the public and patients about HIV/AIDS treatments have led the way in this area.

PLEASE NOTE: This is the report for the OCTOBER 2007 HAI Europe Seminar

HIV is a disease area which has led the way in the provision of independent information sources. Nearly all of these receive some funding from pharmaceutical companies, but do not depend exclusively on them. There is no reason why patient-led information and the organisations that supply it should be biased as long as they provide evidence-based, comprehensive information; they are not dependent (entirely or mainly) on funding from a single industry source; they are transparent about their sources of funding; they have clear guidelines and contractual arrangements about what the funding is for and; the funding is provided as unrestricted grants which do not dictate content.

Conflict of interest

EATG feels that information provided directly to the patient by pharmaceutical companies, or by patient groups predominantly or entirely depending on a single pharmaceutical company for funding, cannot satisfy the requirements for unbiased information.

Information to patients is a hot topic but it is not a new one. It is surrounded by discussion and debate. Currently, the Commission's Pharmaceutical Forum is the main body for discussion on this topic. However, EATG knows its main aim is to improve industry performance as well as to contribute to health. The EU Commission plans to provide information through "public-private initiatives" (PPIs) in which industry plays a significant role. There is now a lot of discussion on that model. There are strong reservations about the establishment of such PPIs. This could be the thin end of the wedge for DTCA. And, of course, it is linked to discussions on industry self-regulation.

Broader information

Patient information about diseases, medication and treatment needs to be much broader. This kind of information should consider culture, education, health literacy and special needs. It is also crucial for health professionals to give and get good health advice, as patients see them as a main source of health and treatment information. The patient/professional relationship must be based on trust and mutual respect and use information that is independent from commercial interests. The underlying concern should be patient safety. In workshops involving EATG, it was agreed that the industry should not be permitted to provide information directly to patients.

Today, EATG has ambiguous feelings about its involvement in the Forum. Its members have felt frustrated by the fact that the topics of discussion are guided by foregone conclusions. There is also a lack of resources to carry out the work and a serious lack of transparency.

EATG wants to look at information for patients outside of the Forum framework. It should be a separate discussion from the Forum and be carried out in a more transparent way.

Promotion of unbiased information:

Experience of a member of the Pharmaceutical Forum

Rita Kessler, Association Internationale de la Mutualité

AIM wants patients to be able to make knowledge-based decisions about their health and demonstrate responsible health behaviour. To achieve this, tools and guidance are needed in order to identify high-quality information. AIM does not want DTCA in Europe.

The organisation participated in the working party's development of a list of quality criteria. At first, given the composition of the group this seemed an impossible task. The members of the working party did not actually work together because their views were so divergent. Instead, the industry representative made a proposal and AIM made its own. If you compare the aims with the final results, one can see that there was strong consensus on most of the criteria, except one, the word "unbiased". In May, during a meeting of the steering committee, AIM's definition of "unbiased" was changed by the other participants.

AIM also worked on the diabetes fact sheet. This caused a great deal of frustration. The fact sheet was produced without taking into account the specific list of quality criteria. No methodology was prepared. It was impossible for AIM to determine who did the main work on this. The process was not transparent. Several times AIM requested evidence-based information to be included in the fact sheet, but it was told that providing such information in footnotes would not be understandable to readers, so it was left out. AIM felt making sure the paper was scientifically accurate should be a priority. Ultimately, some references were added to the document at the end of the process. However, AIM was disappointed with the final result.

As a result, at the second Forum meeting in June, AIM decided to vote against the progress report on patient information. AIM said it could not subscribe to what was said about the work done so far and the work planned. This was a hard decision to make. As a result, the organisation became isolated—a feeling it had throughout the whole debate, in fact. After refusing to sign this report, AIM did not withdraw from the Forum. AIM believed it was possible to disagree and continue to participate in the discussions.

The Forum's set up is unsuited to inclusive discussion and debate. At meetings, 40 people sit around a table, with no microphones and no translation. It is very difficult to follow the discussion, and nearly impossible to debate such complex topics.

AIM expresses serious reservations about the establishment of PPPs (Private Public Partnerships) in the context of information to patients where the pharmaceutical industry would play a major role and does not see the added value of disease fact sheets produced at EU level, as illustrated by the example of the diabetes fact sheet. In the end, AIM felt this was not in the interests of patients and so, felt that it could not give a green light to the report when there were so many topics representatives did not agree on.

Information needs a validation process. AIM wants to pursue the idea of a quality mark, and has requested that the Commission start a process of consideration for this idea. To date, no action has been taken. The first steps in any process should include an analysis of the situation and determination of the needs. Instead, the Forum is skipping these steps.

AIM signed the joint statement with HAI and others that identified good examples of how to provide sources of quality information for citizens.

The view of the British medical profession on the provision of information

Nicola While, British Medical Association

The British Medical Association (BMA) is the UK's leading union of doctors. In total, it represents 68% of all practising physicians in the UK. It also owns the *British Medical Journal*.

The BMA is concerned about patient information and how it is being linked to the advertising issue. In 2002, the BMA worked hard to try to amend the Commission's proposed changes to

Article 88. It is telling that the Commission representative at this meeting did not clearly confirm whether Article 88 is on agenda this time.

The BMA supports the dissemination of information to patients, especially those living with a chronic illness. However, the organisation has strong concerns about the quality and veracity of information contained on internet sites.

Patients want more control before they purchase medicines, yet there is no evidence or research on patient knowledge. The public need to be educated about medicine use, side effects and related issues, using a combination of education and information. An information portal could do this, but it would have to be of high quality, and not under the control of industry. The material would need to be peer-reviewed and the information would need to be objective, evidence-based, reliable, understandable, accessible and relevant.

Consequences of DTCA

The BMA strongly opposes DTCA in all forms. It believes that DTCA encourages the medicalisation of social problems and plays upon normal fears and fear of death. There are reports that doctors are under pressure to prescribe from patients. DTCA is marketing aimed at increasing sales regardless of need.

Advertising to consumers, allowed in the United States and New Zealand, shows that it does indeed influence prescribers' actions. The public can have trouble distinguishing between information and advertising. It takes time to explain why a drug may not work for a particular patient. Advertisements can also overstate a drug's benefits and omit price information.

A review of DCA in New Zealand, found that patients do indeed visit their doctors as a result of advertising, but that such advertising is also raising prescription costs. The money is mainly going towards profitable lifestyle drugs, which squeezes expenditures for essential drugs that have been proven to help patients. It is changing priorities. Media publicity can encourage advertisers to go for blockbusters instead of smaller markets that cover genuine needs. Most advertising dollars go into new drugs with no proven, superior outcome. If DTCA was allowed in the EU, such advertisements would focus on the most saleable drugs.

In the United States, there is a growing debate on rising drug costs. Some say advertising is partly to blame for this. DTCA could jeopardise the primary care system in the UK if it was introduced. It may increase the wealth of advertisers, the pharmaceutical industry and the media, but it can hurt the health system. It is another mechanism to alter prescribing patterns to suit pharmaceutical products.

DTCA is motivated by pharmaceutical companies desire to sell more of their products, it is not based on patients' interests. It is an agenda run by industry, not based on health needs and priorities determined from a health perspective.

The BMA wants consumers to be protected from misinformation. Advertisements are meant to persuade, not inform. Industry should also not be allowed to be involved in a PPI aimed at providing information to patients.

The role of industry in the provision of information

Dr. Scott Ratzan, European Federation of Pharmaceutical Industries and Associations (EFPIA)

Today, people are getting information in different ways, including the Internet and other new communications technologies. Patients have a need and right to information on health and medicines. In the sphere of global health, there is recognition that information is central to public health.

However, there are many challenges to be faced. There is unequal access to information. A lot of the available information is in English and found on the Internet. People want high-quality information sources in their own language. In addition, for those parts of the population, such as the elderly, that do not use the Internet, non-electronic tools need to be made available. There is a need for multiple sources of information.

Many member states stop companies from communicating even basic and legally authorised information about medicines directly to the public. This is despite the fact that companies are legally liable for their products. Ironically, anyone else can disseminate information about drugs, especially through the Internet.

Evidence shows that health-literate patients have a better standard of health. They benefit from better prevention efforts, early diagnosis, treatment and greater adherence. Better informed patients will lead to more successful health outcomes, a more efficient use of resources (e.g., less need for expensive hospital stays and long-term care) and ultimately, to healthier societies. Yet, today there are serious concerns about health literacy in the United States, the UK and other parts of the EU.

Pharmaceutical companies have a unique role to play in the dissemination of information to patients. They have unique disease and product expertise. (The research and development process takes 10-12 years on average.) The industry feels it is an important contributor to health information, together with other providers including healthcare professionals, patients and regulatory agencies. Public private initiatives, involving a range of stakeholders, could be part of a comprehensive information strategy. The acceptability of health information should depend on its quality, not on its source.

Companies should be held to the highest standard of behaviour when providing non-promotional, high-quality disease and treatment information to EU citizens. Self-regulatory schemes and enforcement procedures would be the most practical and beneficial way forward, provided a legal system is put in place allowing the provision of high-quality information from multiple sources.

EFPIA does not support the introduction of DTCA in Europe and it has repeatedly said that it does not seek U.S.-style DTCA in the EU. It does not plan to advocate for it. Its sister trade organisation, PHRMA, based in the United States, also has not advocated for DTCA's introduction in Europe.

Disease awareness—promotion in disguise

Jörg Schaaber, International Society of Drug Bulletins (ISDB)

Why does the International Society of Drug Bulletins (ISDB) have a different view than industry on who should provide information? What are the alternatives to DTCA? And, are they better or worse?

It is hard for a patient to unscramble a drug advert. But, the best advertising does not look like an advert; it is the kind of message you do not think you need to be sceptical about. Disguised promotion can be very successful. There are many different approaches to disguised promotion.

Industry information

Celebrities are used to endorse new treatments and companies write material for Internet sites claiming to be providing information. Some organisations are actually fronts for the industry. These are not just patient groups, but also some seemingly objective scientific groups where the connection is less apparent.

Industry material often gives selective information about a health condition. It may scare consumers into seeking treatment or expand a disease category although there is little evidence of need. Patient groups are also a useful ally for industry. Who is in a better position to ask for new, expensive drugs?

Examples of this type of advertising have a few things in common. There is usually no discussion of the benefit/harm balance. The “dark” side of a drug is always missing. There is always a bias towards drug solutions. Others are produced to promote a new drug. Such advertising leads to overmedication or the tendency towards it.

The question is: Who can be trusted to provide information? Of course, not all of the material produced by the industry is incorrect. But some of it is misleading, and some lacks crucial information. The problem is that it is hard to know which part can be trusted, which makes all industry information questionable, in the end.

There is no alternative to independent information. High-quality information is already available. The problem is not that there is not enough good information. The much bigger problem is that there is so much bad information out there. The good information gets buried under a mountain of misleading, partial and slanted information.

ISDB members publish 60 independent drug bulletins in 34 countries. Other sources include state-run patient information efforts and a number of independent not-for-profit groups. However, good information needs support. There should be independent funding available for good, comparative information. Industry’s influence needs to be better controlled, not just in the area of DTCA, but across all areas.

Transparency is also needed. All drug studies must be in the public domain including pharmacovigilance data. People need the full picture. There is an urgent need for comparative studies including non-drug solutions, where feasible. These aspects should be a required part of the dossier before a new drug can be put on the market.

Patient information: a delicate balance

Erik van Rijn van Alkemade, Dutch Institute for the Proper Use of Medicine (DGV)

Information is a hot topic in the Netherlands today. What is the value of information provided by consumers and patients? They are often the most neglected source of information about medicines. Yet, their own experiences are the most powerful and useful source of information. Most experts consider patients' experiences as highly subjective and therefore unreliable. In contrast, evidence-based information collected by doctors is considered to be highly objective. How does this relate to prescription facts and figures? The variation between doctors is striking. So who is actually objective? The fact that doctors are being subjective does not make patients more objective. How can one balance patients' experiences with doctors' experiences?

Access to patient reports

In 2004, DGV started a patient reporting system. It began as a website for patients to report their own experiences with medicines. In three years, 5,000 reports had been collected. About half focused on side effects, the others highlighted problems related to reimbursement, availability and packaging. Several patient organisations are involved in the project, and the institute produces overviews that are relevant to them.

This past spring, we renewed the website by filing and displaying all of the patient reports. Site visitors choose a drug and can read all of the reports related to it. Each report has a date, describes the experience of the reporter in his or her own words and the way the experience affects daily life.

Publishing these reports was severely criticised by some medical organisations and some media outlets. They questioned whether it was a good idea to report effects when it was not proven that the problem was caused by a medicine. However, we do this with other products all the time and call it a consumer review.

Advertising or Information

Is material targeted at consumers and patients by pharmaceutical companies information or advertising? The debate on DTCA is also happening in the Netherlands. In this debate, DGV promotes independent medical information. It is opposed to direct-to-consumer information coming from the pharmaceutical industry.

If the pharmaceutical industry is allowed to determine which information to disseminate, it will focus on cash cows and blockbusters. The health agenda will be dominated by commercial, not public health interests.

Would it be possible to maintain this view if the majority decide to allow DTCA? From a practical point of view, perhaps DGV would agree to have some kind of patient information coming from the industry provided that it was checked by an independent national body. It would have to be provided on the basis of strict criteria and be objective and complete.

New is not always better

Wil Toenders, Dutch Health Care Insurance Board

The insurance board advises the Dutch Ministry of Health on what should be reimbursed. It is involved in assessing new medicines. The Board also publishes comparative information on a website and makes companion booklets on medicines, called the Medical Compass, in cooperation with patient organisations. These are also available on the website.

Fifty years of drug development have brought some welcome new drugs including antibiotics, insulin and HIV medicines. They prolong life and make significant improvements in the quality of life. However, not every innovation is an improvement. Many new drugs offer little or no new benefits. In several cases, the “classics” are still the first-choice treatment.

The independent drug bulletin, La Revue Prescrire, has assessed medicines for 25 years. It has found that only a small number of new drugs offer a real advantage. Of course, there have been improvements in therapy in some fields, most recently for specialised indications, such as cancer.

Information should be evidence-based and comparative. It should include a drug's price, reimbursement status, how its therapeutic value has been assessed, as well as its efficacy, effectiveness and side effects. New drugs should always be compared to existing treatments.

There is a lack of control concerning randomised trials. In only half of the cases are direct comparisons made. As a result, there is a lack of appropriate, directly comparative trials. For most new medicines, an assessment of their real therapeutic value is not available when they are put on the market. Many more comparisons between drugs could and should be done.

Patient organisations

Valuable information can come out of consultations with patient organisations. The Board often sends them draft reports for comments. However, it is crucial that a company's decision to sponsor a patient organisation be completely transparent. There are a number of initiatives in which pharmaceutical companies are now disclosing their sponsorship, so transparency can come from both sides. It is a worrying trend that, more and more, individual interest is overshadowing the public interest.

Pharmaceutical Forum

The Board has been taking part in the E.U.-working group on relative effectiveness. It is a large group and one with clear industry influence. The Board has been surprised by the poor organisation of the meetings and the poor preparation of the Commission. For example, there are often no microphones available. The beginnings of the working group were quite biased. It was impossible to compare assessments because the industry material was considered confidential.

The outcome of the group could have been far worse. What did emerge from it is rather technical, including the work programme for next year, and the plan to draw up a set of principles for relative effectiveness assessments. The terms of reference have now been agreed.

However, many things still need to happen. There should be more transparency at all levels and publicly accessible databases (on clinical trial data, safety and pricing). Patient reporting of adverse effects should also be encouraged. Importantly, there should be no weakening of the DTCA ban.

Clinical trials should be designed with the aim of providing comparative information instead of being driven from a regulation and marketing perspective. Patients should have access to independent, comparative information. In sum, the EU should promote health initiatives to the same extent as industry competitiveness.

Afternoon discussion

Providing independent information about medicines: What are the solutions for Europe?

Floor debate directed at the European Commission/Pharmaceutical Forum

A lack of innovation

Only 16% of revenue is derived by top companies investing in R&D, according to the sales of new drugs during their first five years in the market.¹ To say we have to rely on new companies for innovation is folly. They can only be relied on to over-promote their products. It is part of industry's attempt to promote its products when innovation has failed.

Public health versus commercial interests

If both Enterprise and the Health Commission are involved in the Forum, many groups here believe public health should take precedence over commercial considerations.

Health literacy

The question of information has drowned out consideration of education and health literacy. Information is being poured over people but it is not easily accessible to people who do not have a concept of how to use it. It is disappointing that the EU and national governments pay no attention to educating children and adults about their health. Without these concepts, people cannot use information appropriately. Has the issue of education ever been considered or discussed in the Forum's plans?

Involving other groups

DG Sanco runs an open health forum. All NGOs with an interest in public health gather there on a regular basis. Why has that group not been convened to discuss health information? Why did DG Sanco or Enterprise not think of that?

There was some discussion on the diabetes model package and the quality criteria. Many groups responded to that consultation and were shocked by the poor quality of the material presented. It lacked comparative information about treatment options as well as approaches patients could take themselves. It included no quantitative information on what would improve their condition in the short term or make it worse.

¹ "Research of the Top 20 Companies investing in R&D Shows Revenue derived from New Products Accounted for Just 16% of Total Revenue in 2006". Bio-Medicine. <http://www.bio-medicine.org/medicine-news-1/2007-2008-Pharmaceutical-R-26D-Factbook-Published-by-CMR-International-is-Now-Available-1872-1/>. 24 September 2007.

The quality criteria for consumer information must meet education goals, yet the quality criteria produced from this consultation does not. There is real frustration that we are watching the process from the outside. At this meeting, the same statements were made as in 2001, saying that this push for patient information is absolutely not about advertising. Yet in 2001, when the proposal was unveiled, it was in fact about a change to Article 88. Is the legislative change currently under consideration related to Article 88?

Responses from the floor directed at the industry:

Staying competitive

It is ironic that EPFIA's interest in patient information is presented as altruistic, and that it was stressed that the Commission is promoting the need for greater competitiveness. On what level does it depend on the industry's ability to inform consumers directly about their products? Are there any concerns about the volume of health promotion material directed at consumers? Consumers need trusted, valid information.

EFPIA says it does not want U.S.-style DTCA and that PhRMA member companies also do not want to see it in Europe. Yet, many of the U.S.-based PhRMA members have set up websites about their medicines. If you are against DTCA in Europe, why not block access to U.S.-hosted sites from European addresses? These sites are, in fact, a form of DTCA.

Companies in Europe are creating websites too. The problem is that there is a lack of law enforcement. We do not need more of this material, we need less. People have a right to information. But that has nothing to do with the right to advertise. There are limitations; no one can claim that there is a general right to advertise.

Screening

The push that industry makes about screening for possible health conditions is very suspect. Some of it is effective, but screening has become an industry. It does not actually save lives on the scale it is claimed. People should be able to say this is not for me, it is not necessary.

A lack of democracy

When industry says it has a role to play in the provision of information, it reminds me of George Orwell's book *Animal Farm*. That is, some are more equal than others. The Pharmaceutical Forum has a lot of influence on the Commission and how the legislation will be drafted. It is a very select approach to say the least. It does not seem to be a fair balance. This has to do with public-private "partnerships". The Forum itself is already a PPI. The Commission selected a few interest groups to help draft the laws and make changes. This is a problem. These participants are not elected. How is this political process being checked? We talk about information and transparency, but the same was true for the G10 Group before the Forum.

Reaction of Christian Siebert, the European Commission

The Forum's work and composition

It was clear from the start that the Forum's discussions and reflections on patient information have little to do with DTCA. In terms of the Forum's credibility and its composition, I think we had transparent criteria when it was created. Apart from the Member States, stakeholders that are continually and generally concerned with the Forum's themes were chosen. Some groups only

focus on these issues periodically and, therefore, were not included. The Forum accepted 10 stakeholder - groups representing public and private interest - that fulfilled these criteria.

The Pharmaceutical Forum has two objectives: industrial competitiveness and public health. These are equal priorities. This is documented and guaranteed by the fact that two commissions are involved. The fact that Directorate General for Enterprise and Industry is in charge of the pharmaceutical legislation does not mean that legislation is made to stimulate competitiveness only. Medicines are authorised because they are good for public health and are considered safe.

Information works more efficiently when patients are educated. This point was made in a working group and participants agreed that this was true. However, in our work, we have to focus on specific items like quality issues. With such an ungainly vehicle as the Forum, having so many interests involved, progress can only be made if you look at a limited part of the task. The Forum has not worked on the question of education but it is an important subject and maybe it is something for member states or the regions to take up.

We have discussed and presented the Forum's activities in a number of fora. I do not believe there is an unwillingness there to work in a transparent manner. Any group not involved in the Forum directly can also take part in the public consultations. No one is preventing anyone from expressing their views.

Model packages of information

Public consultations have concluded that there is still work to be done on these pilots of disease/condition fact sheets. This work should be carried out by a smaller group, perhaps at national level. Whether we do further information model packages and how remains to be seen.

Quality criteria

The quality criteria, by contrast, have achieved quite a level of sophistication. They should fulfil expectations of general criteria. Now it will be important to see how they can be applied.

Changes to Article 88

As regards legislative change, the Commission now has to come up with a report which summarises what exists in the field of information on medicines in Europe. Then, the next step will be the question of possible legislative change. However, as I said before, both Commissioners, have said that there is no question of changing the ban on advertising for prescription drugs. It will remain as it stands.

1) What role did EFPIA play in the drafting of the diabetes information leaflet?

2) What type of information would EFPIA like to get out to people?

Reaction from Dr. Scott Ratzan, EFPIA:

Industry's role in the fact sheet

I believe this work was carried out by patient groups. I do not believe that EFPIA had an active role in giving information. It was produced by the Commission.

Staying competitive

The G10 process took place before the Forum and focused on competitiveness for the benefit of patients. The better patients are informed, the healthier they will be. Today, there are more than 25,000 peer-reviewed medical journals. We all know which ones are in the top ten. Having so many does not hinder progress. Better information will rise to the top and it will be the information that people trust. A plethora of information will increase the quality. Look at the growth of websites alone. Some are trusted sources of information. During epidemics, governments do not always rise to the occasion and others will emerge as trustworthy sources. If we have limited sources or try to funnel information, people will have less information at a time when they need it most.

Guidelines

Industry already has some Internet guidelines but maybe it has to update them. There are also codes of conduct, though not everyone follows all the rules. We can all do a better job on quality information. We need to talk about quality and what it could be. We believe everyone providing information should be disseminating quality information.

PPIs

Better information is the foundation. Partnerships are the way of the future. We need to figure out how we are all partners in society. Hopefully, over time, industry will no longer be seen as a pariah. Our information is of the same quality and validity as that made by others.

Industry's information goal

We are trying to look at what people want in terms of reference information. This includes information about prescriptions, medicines, treatment compliance, prevention, and where to find additional information. People need treatment awareness. There are a variety of ways to present this material well. Often it can be done with the support of or at the initiative of the government. Whatever the source, all of the information has to be validated, evidence-based and follow quality criteria. Some will appear on websites, other information will come through printed sources. That is the kind of thing we are looking at.

If it means a change to Article 88 for us to be able to provide the kind of information we think people need, then that is what we would have to do. But I would be in favour of another way to get out the information people need.

Disclaimer: HAI Europe is still awaiting confirmation of the speakers' texts from the following speakers:

Didier Rod, medical doctor and former member of the European Parliament (MEP)

Dr. Scott Ratzan, European Federation of Pharmaceutical Industries and Associations (EFPIA)

PLEASE NOTE: This is the report for the OCTOBER 2007 HAI Europe Seminar

SPEAKER BIOS

Teresa Alves was involved in the pharmacy student association movement, at local, national and international levels throughout her studies at the Faculty of Pharmacy, University of Porto. She subsequently held the positions of Project Coordinator and Communications Manager at the International Pharmacy Federation (FIP), an NGO representing pharmacists' and pharmaceutical scientists' associations worldwide.

Her career placements were connected to public health issues and as a result, she became particularly interested in topics related to rational drug use and health policies, their implementation through tailored interventions and their impact on the local community and the population at large. Teresa completed a Public Health Masters at the Netherlands Institute of Health Sciences, Rotterdam in 2006, where she conducted a research project assessing the extent and variation of self-reported polypharmacy in Europe.

Since September 2006, she has been working at Health Action International Europe for the European desk and managing campaigns on medicines' policy issues. She has recently been appointed HAI Europe Coordinator.

Rita Kessler was a Project Manager at ACME, European Association of Co-operatives and Mutual Insurers, in charge of studies and communication from 1990 till 1998.

She has worked as a Project Manager at Association Internationale de la Mutualité (AIM) since 1998, where she is in charge of the coordination of different working parties, especially the pharmaceutical expert group as well as the European affairs committee.

A native of Belgium, she has a Masters Degree in Psychology (1988), Post-graduate Business Management and Administration Degree (1989) and Law Studies (1993).

Fiona McLean is the Managing Coordinator of the European AIDS Treatment Group (EATG). She is a member of EATG's Policy Working Group and has been actively involved in the debate on Information to Patients. She represented EATG in the work of Pillar III (Information to Patients) of the Pharmaceutical Forum and co-organised two workshops on Information to Patients together with PGEU and CPME.

Barbara Mintzes is a long-time HAI Europe member, outgoing Chair of the Board of the HAI Europe Association, and HAI-Europe staff member from 1991 to 1996, responsible for publications, press and communication. She is also the author of the 1998 HAI Europe report, 'Blurring the Boundaries: New Trends in Drug Promotion'.

She is an Assistant Professor in the Department of Anesthesiology, Pharmacology and Therapeutics at the University of British Columbia, in Canada. She holds a PhD in health care and epidemiology from the University of British Columbia. Her doctoral research examined the effects of direct-to-consumer advertising (DTCA) on prescribing decisions in primary care in environments with and without legal DTCA. She works with the Therapeutics Initiative at the University of British Columbia, and Canada's Common Drug Review, carrying out systematic reviews of the safety and effectiveness of new drugs. These reviews help to inform public drug reimbursement decisions. She also jointly coordinates a HAI Europe and World Health Organization project on educational initiatives to teach medical and pharmacy students about drug promotion and was based in Amsterdam as a research consultant for HAI Europe from September 2006 to March 2007.

Other areas of interest include European and international regulatory issues, drug safety, and women and pharmaceuticals. Barbara Mintzes is Vice-President of DES (diethylstilbestrol) Action Canada and member of the Steering Group of Women and Health Protection in Canada and is on the Advisory Board of Association Mieux Prescrire in France.

Ilaria Passarani is the Health Policy Officer at BEUC, the European Consumers' Organization. Before joining BEUC in 2006, she worked in Brussels as European health policies advisor for the Veneto Regional Government.

She graduated in Economics from Bocconi University in Milan.

Representing the views of forty reputed, independent national consumers' organisations from thirty European countries, BEUC lobbies for the interests of European consumers to be placed at the heart of the EU policymaking.

Scott C. Ratzan, MD, is Vice President, Pharmaceuticals and Global Health, Government Affairs, Europe for Johnson & Johnson. He is responsible for government affairs support for pharmaceutical companies in Europe. He is a member of the Janssen-Cilag European Management Board and Chairs the European Public Affairs Committee. He also leads Johnson & Johnson's government affairs efforts in Global Health.

His most recent position was Senior Technical Adviser in the Bureau of Global Health at United States Agency for International Development (USAID), where he developed the global health communication strategy for U.S. funded efforts in 65 countries. He has also served on committees for the World Health Organization (WHO), the Institute of Medicine (IOM) and a variety of other organisations.

Scott founded the Journal of Health Communication: International Perspectives in 1994 and remains the Editor-in-Chief. He has appeared on Good Morning America and Nightline. Scott has had articles published in the Wall Street Journal, New York Times, Financial Times and European Voice. His books include the Mad Cow Crisis: Health and the Public Good, Attaining Global Health: Challenges and Opportunities and AIDS: Effective Health Communication for the 90s.

Scott maintains faculty appointments at Tufts University School of Medicine and George Washington University Medical Center as well as the University of Cambridge in the UK and the College of Europe in Belgium.

He received his MD from the University of Southern California; MPA from the John F. Kennedy School of Government, Harvard University; and MA from Emerson College and an A.B. in political communication from Occidental College.

Tim Reed is Director of the NGO Health Action International (HAI) at the regional office in Amsterdam. He was the Director of the national NGO Searchlight in the United Kingdom from 1984 till 1994. He worked as a lecturer in the Sociology Department at the University of Sussex, from 1997, with expertise in European pharmaceutical policy and he published several articles during that period. He has been engaged in the formation, proposal and delivery of major international pharmaco-political research projects.

Tim is British and has a BA (Hons) in Sociology with Development Studies from the University of Sussex (1997), with a specialisation in the sociology of health and development and the political sociology of pharmaceuticals. He has a D.Phil. in Political Sociology on 'The regulation of Medicines in Central and Eastern Europe'.

Dr. Didier Rod is a former Member of European Parliament for the Greens (1999 to 2004), where he took part in the Commission on Public Health and Consumer Defence. He has enjoyed a long career in the medical world and has headed or managed several medical research laboratories including ones on pharmacovigilance and medical communication. Currently Dr. Rod acts as an adviser to the magazine 'Prescrire'.

A native of France born in 1950, he completed his medical studies at CHU Pitié Salpêtrière (1977) and finished his PhD in 1980.

Jörg Schaaber is a sociologist and master of public health. He works for BUKO Pharma-Kampagne, a German NGO working for rational drug use. Schaaber is the editor of Pharma-Brief and co-editor of Gute Pillen–Schlechte Pillen, the first independent lay bulletin on drugs in Germany.

He was the chair of HAI Europe executive board for many years and is now a member of the executive committee of the International Society of Drug Bulletins (ISDB). Schaaber is a patient representative in the drugs committee of the German public health insurance system (Gemeinsamer Bundesausschuss).

Christian Siebert is Head of Unit in the European Commission, Enterprise and Industry Directorate-General, Unit 'Competitiveness in the Pharmaceutical Industry and Biotechnology'. The activities of the unit includes the Pharmaceutical Forum, a follow-up to the 'G10 Medicines' group's policy recommendations on access of patients to medicines and on improved conditions for innovation in the European pharmaceuticals industry. The unit also contributes to the development and implementation of the European Commission's policy document and action plan 'Life Sciences and Biotechnology—a Strategy for Europe'.

He joined the European Commission in 1991 and held previous positions in the Enterprise/Industry Department, dealing with biotechnology, the food industry, cooperation with Central/Eastern Europe and with GATT/WTO matters. He has also been Assistant to the Director-General for Industry.

A native of Germany (born 1957), he graduated (MA) in Political Science and Economics at the University of Mainz (Germany), before completing post-graduate studies at the College of Europe (Bruges, Belgium).

Wil Toenders graduated as a pharmacist with a subsidiary in general practice in 1983 and conducted research into the influences on prescribing behaviour of general practitioners. After practising in a pharmacy in a healthcare centre in Amsterdam, he became editor of the Dutch Drug Bulletin in 1990 and was General Secretary of the International Society of Drug Bulletins from 1996. In 1999, he joined the Dutch Healthcare Insurance Board as a pharmaceutical adviser. Since 2004, he has been the secretary of the Dutch Reimbursement Advice Committee, the independent expert committee responsible for advising the Ministry of Health on the reimbursement of medicines.

He is a permanent referee for the Dutch Medical Journal (NTvG) and has been the author and (co)-editor of several books: 'All about the contraceptive pill', 'Pharmacotherapy for HIV and AIDS', 'Medicines that you should not use' and the 'Pharmacotherapeutic Compass – a guide for prescribers'. At present, he is the editor of the 'Medicine Compass – for patients'.

Erik van Rijn van Alkemade (1951) is head of the Department of Information and Transparency at DGV, the Dutch Institute for Proper Use of Medicine. His special interests are patient information, patient reporting and monitoring the pharmaceutical industry. He studied PR and Marketing and was, for long time, employed at the Dutch consumer association Consumentenbond.

Nicola While is the EU Liaison Officer for the British Medical Association, representing UK doctors at the European institutions. Prior to joining the BMA in 2006, she spent four years working for the Brussels-based offices of various UK regional authorities.

Nicola has a BA (Hons) degree in European Studies and French and a MA in International Politics.