

Introduction

In her introduction, **Dagmar ROTH-BEHRENDT** (PSE, Germany) stated that there probably was general agreement amongst all parties on patients' right to access to information, but that the viewpoints might differ as to who is providing this information, who is analysing it, and what appropriate information really is.

She regretted that the European Commission had delayed the adoption of its *Report on current practice with regard to provision of information to patients on medicinal products* which was due to be presented last April. "Any legislative proposals resulting from this report will now probably be too late for adoption during Parliament's current legislature ending in mid 2009", said Roth-Behrendt.

Expectations of Society

The first part of the conference chaired by **Jorgo CHATZIMARKAKIS** (ELRD, Germany) looked at the "Expectations of Society" and brought together top officials from the European umbrella organisations of patients, consumers, medical doctors, pharmacists and pharmaceutical industry.

Chatzimarkakis made it clear that the conference was not about advertising, although much time in the *Information to patients working group* at the High-Level Pharmaceutical Forum (set up by Vice-President Günter Verheugen and Commissioner Marcos Kyprianou in 2005) was spent on delineating information and advertising.

Anders OLAUSON, the President of European Patients' Forum (EPF) said that the provision of information to patients was a priority issue for the millions of patients he represented in Europe, and that he was looking forward to receiving valuable information from pharmaceutical manufacturers on their products, however only after this had been properly validated. The information should moreover be non-promotional and should be delivered to the patients in a correct manner.

Jim MURRAY, the former Director General of the European Consumers' Organisation (BEUC) strongly supported the right of access to quality, independent and balanced health information, including information on medicines, as an important contribution to the autonomy, dignity, health and wellbeing of patients and citizens. "This can be achieved only", said Murray, "by developing a broad health information strategy rooted in a wider and coherent health policy. At EU level, this can best be done in cooperation with Health Ministers through the Open Method of Coordination¹. The Health Council is the forum for doing this." On the other hand, Murray said on behalf of BEUC that "we do not believe that it is possible in this context to make an effective distinction between information and advertising. However, even if a workable distinction could be made, we would still be against the lifting of current restrictions on the information that medicine companies can give directly about prescribed medicines."

The President of Standing Committee of European Doctors (CPME), **Daniel MART**, stressed that the Patient-Doctor relationship is at the core of the healthcare process. "Doctors welcome the well-informed patient but they have major problems with a misinformed patient. Doctors

¹ The Open Method of Coordination (OMC) is a relatively new intergovernmental means of governance in the European Union based on the voluntary cooperation of its Member States.

moreover have a direct interest in helping to guarantee the conditions to produce validated high-quality information, and this information should be provided not only on medication but also on diseases and prevention”, said Mart. “The question is who delivers this information and whether it should include explanations on how to treat a disease, whether ethno/cultural differences being considered and what different levels of information we want and for which target groups.” The CPME “would gladly participate in the organisation of a stakeholder platform which should explore ways to promote and exchange good practices in order to overcome barriers to equal access to information,” concluded Mart. “The actions developed within the Pharmaceutical Forum should be included in an overall strategy for information to patients on diseases and treatment options. These outcomes should be used as input for the further development of Article 88a [of Directive 2001/83/EC].”

Leopold SCHMUDERMAIER, the President of the Pharmaceutical Group of the European Union (PGEU), stressed that pharmacists fully endorse patients’ right on access to high-quality information. “People now often turn to family members or the Internet for information on health, and this has totally changed the relationship between health professionals and patients,” said Schmudermaier. In his opinion, the quality criteria developed by the Pharmaceutical Forum were adequate for the development of high-quality information. This means that the information should first be validated and that it should be provided to patients by a trusted source. Schmudermaier called for action at EU level so that the agreed quality criteria could be implemented in all Member States.

Brian AGER, Director General of EFPIA was pleased that “After so many years of debate in different fora there now seems to be widespread agreement that communication with European patients and the general public on health issues and prescription medicines should be improved with the objective of having better informed patients.” He stressed that EFPIA “has not, is not and will not be asking for U.S.-style direct-to-consumer advertising of prescription-only medicines, but that current restrictions preventing companies from communicating legally authorised information should be lifted.”

He concurred with previous speakers that there was an urgent need for reform in the European Union with the primary goal of reducing the current inequalities among different population groups and between EU Member States in accessing high-quality information. “We firmly believe that this can only be achieved through “patient information partnerships” (as they already exist in few Member States) involving all stakeholders who commit themselves to providing quality information of the highest standard. The industry, which has unique disease knowledge and product expertise (having researched and developed their medicines over 10-12 years per approved product), stands ready to play its role in the provision of non-promotional high-quality information in order to respond to citizens’ legitimate right to benefit from such information,” concluded the EFPIA Director-General.

AESGP Director General **Hubertus CRANZ** called for and “adequate interpretation of the current legislative provisions with regard to the labelling of medicinal products. This should allow the addition of non-promotional information on the package so that companies would for instance be allowed to mention a website address which may provide valuable additional information in relation to a particular condition. Smoking cessation is a concrete example where this would be useful”, said Cranz.

The AESGP Director General further explained that it is AESGP's political wish to expand responsible self-medication/self-care in order to better respond to the expectations of the citizens to take care of themselves (consumer empowerment) and to reduce the cost burden for social security institutions.

Cranz drew particular attention to the important role of health professionals in providing information on non-prescription medicines. In order for medical doctors and pharmacists to reach their full potential to support European citizens on the appropriate use of these medicines and the diseases they treat, Cranz pointed out that there was a need to improve the curricula and post-graduate training programmes of these health professionals with regard to patient communication. "Adjustment of the curricula is possible, said Cranz, "and we should use the existing options. In this context, AESGP is committed to contributing to these training programmes and the association already has a longstanding cooperation with the European pharmacists in this area."

What legal framework can we build in Europe?

In the second session chaired by **Dagmar ROTH-BEHRENDT** entitled *What legal framework can we build in Europe?*, the Director General of the European Commission's Directorate-General Health and Consumer Protection, **Robert MADELIN**, insisted that "we should reflect on the wider challenges in the area of health today, and in particular the information challenges".

The EU's new Health strategy laid down in the White Paper "Together for Health" adopted on 23 October 2007 sets out a number of areas such as e-Health applications which can be used to support the empowerment of citizens in health. In this context, the Commission is developing a comparable European Health Information and Knowledge System to support policy making to reduce inequities in health. "Instead of narrowing our sights to information on just one special area of health technologies – pharmaceuticals – we should consider how health related information can be provided in such a way that citizens and authorities can trust it," said Madelin.

On information to patients, the Pharmaceutical Forum – which has been a useful platform for stakeholder collaboration to build trust – has according to Madelin so far achieved two main objectives.

- On access to information on health care settings, a set of core principles of good quality information has been agreed. The Forum working group is now developing a methodology to implement the quality principles.
- The second objective has been to contribute to the legislative process on information to patients on pharmaceutical products. Madelin said that the Forum had developed some useful elements to be considered when discussing the legal framework, and in particular the core principles of good quality information. "The Forum working group is now focusing on good practices at national level regarding partnerships. "Sweden with a specific example of a partnership called FASS and a number of other Member States, have developed or are in the process of developing partnerships which bring together information on pharmaceutical products. The Forum has provided a mechanism to share those experiences."

Concerning the distinction between information and advertising, Madelin said that this had also been discussed in the updated *TV without Frontiers Directive*, which lays down some basic principles governing advertising, and at the same time simplifies and liberalises rules on inserting advertising in TV programmes and on new advertising techniques.

Madelin concluded that the Forum process had provided a useful platform to discuss a wide range of issues related to information to patients, and that trust and confidence have to be ensured in any system which provides information to European citizens.

Christian SIEBERT, the Head of Unit for Competitiveness in the Pharmaceuticals Industry and Biotechnology at the European Commission's DG Enterprise and Industry, mentioned that while recognising the primarily role of national authorities in ensuring the provision of information to their citizens, the Commission has been fully engaged in favour of promoting access to high quality information.

In the framework of the Pharmaceutical Forum, Member States and stakeholders have reached a large degree of common understanding on needs and challenges in terms of access and quality of information for patients. In addition, the working group has been engaged in a constructive approach to deliver practical elements to support Member States in enhancing access to high quality information. This includes the recognition of the role of health professionals in the delivery of information to patients and the identification of good examples (in pharmacies, primary care settings or hospitals) which could contribute to reducing the existing barriers to high-quality information. A set of core quality principles for information and a methodology for their use is being produced, said Siebert.

Concerning the *Report on current practice with regard to provision of information to patients on medicinal products* and the possible changes to the legal framework which might result from it, Siebert provided the following insights.

During the consultation on the Commission's draft report earlier in 2007, 73 contributions were received. There was an emerging consensus that:

- information provision to patients should be improved
- the ban on direct-to-consumer advertising should be retained
- the internet is a good but not the only channel for providing information to patients
- there is a clear need to adopt common standards and quality criteria for information provision.

There were mixed views on the distinction between information and advertising and on the possible best mechanism to ensure quality of information and enforcement of rules.

The report has been finalised within the Commission and is awaiting final adoption by the College of Commissioners for transmission to the European Parliament and the Council by the end of 2007.

To ensure further harmonisation in the rules concerning the provision of valid and high-quality information to patients on medicinal products authorised in the EU, said Siebert, the Commission has announced its intention to adopt a legislative proposal on information to patients by the end of 2008. The general policy objectives of this legal proposal should be:

- to establish a framework for providing citizens of EU Member States with high-quality and non-promotional information about the benefits and the risks of their medicines
- to maintain the ban on direct-to-consumer advertising of prescription medicines
- to maintain the confidence of citizens, regulators and healthcare professionals, while putting the interests of patients first
- to avoid unnecessary bureaucracy, in line with the principles of Better Regulation.

As an intermediary step, said **Rui SANTOS IVO** of DG Enterprise and Industry's Pharmaceuticals Unit, the Commission is preparing an assessment about the possible impact of any legal proposal. The aim of the impact assessment started in May 2007 is to identify the main options for achieving the objectives mentioned above, to analyse their likely impacts and to outline advantages and disadvantages of each option and examine possible synergies and trade-offs, also in relation to different types of information.

According to Siebert, a great challenge in the forthcoming legal proposal and in the impact assessment is to make a differentiation between informing and advertising. This indicates clear orientations to the framework to establish clear rules on what type of information can be provided, who can provide it, how it can be provided and on enforcement mechanisms. All the information provided to patients should respect the quality criteria agreed at the Pharmaceutical Forum in that it should be objective and unbiased, patient oriented, evidence-based, up-to-date, reliable, understandable, accessible, transparent, relevant and consistent with statutory information.

Noël WATHION, the Head of Unit for Post Authorisation, Evaluation of Medicines for Human Use at the European Medicines Agency (EMA), explained that the Agency has since more than 10 years undertaken various initiatives to improve information to patients. Although the large majority of these result from the implementation of Community legislation (medicinal products approved through the centralised procedure), the Agency has also explored complementary activities to contribute to the informed patient concept. This has resulted in deliverables such as improved transparency in relation to the Agency's work, more patient friendly information and the launch of the EudraPharm database.

To ensure an appropriate coherence and coordination in relation to the different types of information the EMA provides, and the tools with which this information is communicated, the EMA takes due account of patients' expectations as expressed in the framework of the EMA Scientific Committees' Working Party with Patients' and Consumers' Organisations.

To ensure the hard endpoint - the rational use of medicines –Wathion mentioned that a wide range of issues will need to be addressed, such as information to patients; general knowledge and education; risk minimisation; dissemination channels, etc.

Amongst the proposals for further consideration aiming at reinforcing the informed patient concept and requiring legislative change, Wathion mentioned that “one should acknowledge that the main tool to inform patients, the package leaflet, is not really – in its current form – the most appropriate tool to provide patients with the best possible information on the use of a medicine. One should explore how any revised statutory information can be supplemented with additional elements to better inform patients”, said Wathion.

The development at EU level (e.g. the EMA) of a ‘standardised information package’ for a particular medicine (on top of legal documents such as the SPC, the package leaflet and the EPAR) to be extracted from the various Eudra databases held by the EMA (e.g. EudraPharm, EudraVigilance, EudraCT) should be considered. This standardised information package should then be made available in all EU languages at local level, either for direct use in primary health-care or to be adapted to the specific needs of primary healthcare in a particular Member State. “The pharmaceutical industry could participate in the adaptation to the local needs and the subsequent dissemination of the information at local level. In the first instance, this should be limited to centrally authorised products,” concluded Wathion.

Per MANELL of the Swedish Association of the Pharmaceutical Industry explained that Sweden has a longstanding tradition of providing information to patients. This is done in an agreement between industry and the Swedish Association of Local Authorities and Regions. The main vehicle through which this is done since 1983 is the Patient FASS, a book with product information on all medicines authorised in Sweden as well as treatment options. The Patient FASS was upgraded to an Internet version in 2001, which is also available for disabled patients. The publication has gained the trust of the Swedish public as only authorised information is allowed to be published. All Swedish pharmacies obtain their information from FASS. “The industry is thus assuming its role as a quality information provider, and the self regulatory quality assurance system has proven its value,” said Manell. Moreover, an agreement was signed between the Swedish associations of healthcare providers and the pharmaceutical industry in June 2007 on the supply of medicines information in the electronic media.

Manell mentioned that a new initiative called “My Medicine” was to be launched in Sweden the following week. This could send information to a person’s mobile phone and would “firmly set the patient in the driver’s seat”. He said that the Swedish way of providing information to patients could be an example for other countries in Europe.

Martin Clemens AUER, Head of Section at the Austrian Ministry for Health, Family and Youth, said that it was important to see the provision of information to patients in a wider perspective and that it was equally important to ensure access to healthcare in general. This should include information on prevention, the availability of healthcare providers and even personal health records. Auer mentioned that the Austrian government had decided to create a portal on health records to which general health information could be added. He was nevertheless convinced that this was a task for the public administration. “But only if strict quality criteria are met is it appropriate to spend public funds on such an initiative,” warned Auer. He admitted that Austria is several steps behind Sweden on this point, but that the technical criteria for the web portal had already been developed.

Austria supports the building of a network of national authorities to agree on quality criteria in order to arrive at a European library on health information. Auer mentioned that Austria will pilot such a project together with the EMEA and/or private partners.

Discussion

In the ensuing discussion, Madelin mentioned that the existing EU health portal (http://ec.europa.eu/health-eu/index_en.htm) could be seen as the beginning of a ‘FASS portal’. He did not see any reason not to create a European library on health information although he did not mention who should look after such a library.

As to the question raised by Roth-Behrendt whether ‘hard’ or ‘soft’ law was needed to address the provision of information, Siebert replied that the Pharmaceutical Forum’s ‘quality criteria’ could be seen as a form of ‘soft law’ and that the European Commission would be coming forward with a ‘hard law’ legislative proposal in October 2008 bundling all required changes to the pharmaceutical legislation, not only those on information to patients. This was not quite early enough retorted Roth-Behrendt and warned that any proposal being put forward after mid 2008 would be ‘lost’ for the current Parliamentary legislature.

It was also stressed that it would be important for Ministers agreeing on certain points at the Pharmaceutical Forum to feed this agreement through to their civil servants given that these are sometimes unaware of such agreements when representing their country at Council level. Siebert stressed that the Forum's Steering Committee could help ensure consistency on this.

Conclusions

In summing up the main agreements emerging from the conference, **Jorgo CHATZIMARKAKIS** said that it was clear that a validation mechanism of patient information was needed, that both soft and hard law would be helpful in this context, that patient information could best be provided in an international approach and that stakeholders could probably not take care of this validation alone.

Any changes to the current legislative system concerning patient information should commence with a reform of the patient information leaflet to make the information more accessible for the patient.

All forms of patient information should come from a trusted source and any information provided should be validated based on data included in the current EU library.

Concerning health education in general, Chatzimarkakis said that this should be started as early in life as possible, ideally already in primary school, and that it should be continued throughout the educational system including universities.

There was also agreement that the communication skills of medical doctors and pharmacists should be improved and that the mass media should be trained to educate citizens on how to take care of their health.