



Event	Health and Consumer Intergroup – Information to patients
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Date and place	3 rd October 2006, Brussels
Organised by	EPHA, BEUC
Notes	Presentations and background information: http://intergroup.epha.org/article.php3?id_article=15

Ms Ayuso Gonzalez MEP (EPP-ED Spain) co-chair of the Intergroup, welcomed participants and introduced the speakers. She mentioned that the High Level Pharmaceutical Forum, established jointly by DG Enterprise and DG Health and Consumer Protection, met for the first time on 29 September 2006. One of the working groups will look into Information to Patients. The expected outcomes are a consultation paper and a Communication to the European Parliament and the Council.

The intergroup meeting aimed to provide some answers to the following questions: what is the difference between information and advertising? What criteria shall be used to define information to patients? Who shall provide information to patients?

Although Gus Cairns from the European Aids Treatment Group could not be present, a summary of his contribution is available at the end of this report.

1. Presentation by Priya Bala, Consumer's international - “Transparency and accountability in drug information for consumers”

Priya Bala outlined the key information pathways through which consumers receive drug information. She stressed that drug information must comply with guidelines set out by the regulatory authorities. It should be reliable, accessible to all and should highlight alternative treatments to drugs. Ms Bala suggested that whilst all stakeholders agree that information pathways do need to be improved there is much debate about how to provide information and who should provide it.

Ms Bala made reference to the need for a clear distinction between information and advertising as the two are being blurred by marketing tools used by the pharmaceutical industry. Ms Bala presented CI research on drug promotion which concluded that pharmaceutical companies are not best placed to provide information to patients. The key findings from the research demonstrated that pharmaceutical companies show limited transparency in reporting key Corporate Social Responsibility information on their marketing practices. New marketing tactics do not favour rational drug use by consumers and breaches of regulations and CSR codes occur frequently showing weak industry self-regulation.

Ms Bala concluded her presentation by stating that Consumers' International is reluctant to support initiatives in favour of relaxing the DTCA ban in the EU. She emphasised the need for independent and reliable sources of information which put consumers' health above profits. She urged EU decision-makers to monitor and support EC directives regulating drug promotion, to critically evaluate the comparative performance of EMEA and to move the regulation of drug promotion to the

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Directorate for Health and Consumer protection as opposed to the Directorate General for Enterprise and Industry where it currently stands. She also underlined the importance of collective action by consumer organisations, government authorities, the EU and the pharmaceutical industry to develop uniform guidance and indicators on CSR reporting for drug promotion, to ensure industry compliance with CSR codes and regulations, to make a clear distinction between information and advertising and to implement alternatives to self-regulation.

2. Presentation by Barbara Mintzes, Health Action International – University of Columbia, Canada - “Improving information to patients – the way forward”

Barbara Mintzes' presentation was based on the Declaration on Relevant Health Information for Empowered Citizens, co-signed by Health Action International (HAI), BEUC the European Consumers' Organisation, the International Society of Drug Bulletins (ISDB), the Association Internationale de la Mutualité (AIM) and the Medicines in Europe Forum (MiEF). The declaration was put together to ensure there is a clear distinction between information and advertising, and because there is a need for broader representation and more open procedures within the Pharmaceutical forum.

Ms Mintzes emphasised that relevant health information should be reliable, comparative and accessible to all. She then showed a number of different advertising campaigns which had been presented in the guise of information by various pharmaceutical companies to promote the use of drugs for different diseases. Ms Mintzes highlighted that companies never use the word advertising but use 'information' to actually promote their drugs. She also asserted that information tainted by commercial bias is a major threat to scientific evidence and to public health. Manufacturers do have a role to play in information provision in terms of the patient information leaflet (PIL) and packaging, but not in comparative treatment information or disease-oriented information. In addition, she stressed the need for transparency in medicines regulation and full publication of all clinical trials. The major threat to public information access occurs when manufacturers are selective with the information they publish from clinical trials, safety updates and observational data.

Ms Mintzes added that there are currently many positive patient health information initiatives including tools for information providers, such as quality criteria guidelines for patient information, initiatives by public health authorities, independent consumer and health professional organisations and services to meet individual needs. Ms Mintzes concluded by highlighting the dangers of direct-to consumer advertising with the example of the campaign for the Vioxx drug.

3. Debate

Jorgo Chatzimarkakis MEP (ALDE Germany) opened the debate by informing the Intergroup that Mr Chatzimarkakis, Mrs Grossetête MEP (PPE-DE France) and Dagmar Roth-Behrendt (PES, Germany) represented the European Parliament at the High Level Pharmaceutical Forum. Mr Chatzimarkakis explained that free access to information is available on the internet if patients speak English. This situation creates an information divide, which denies all citizens the right to information. In addition, information on the internet is currently not being validated and there is no way of knowing whether information accessed via search engines is biased or not. He calls for an end to this situation. He believes Public Private Partnership (PPP) could play a role in validating this information. The EMEA could also be considered as an information validation body although they lack resources to do so.

He agrees there is a need to distinguish between information and advertising and that this must be agreed by Parliament and the European Commission. He also stressed that Italy, Germany and France are in favour of some changes and that the smaller member states do not have a clear position on the issue.

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Didier Rod (MEP from 1999 to 2004) stated that in the last parliamentary term, 70% of parliamentarians voted against legislation to provide direct information to patients. He emphasised that it is essential to know who validates the information and called for an independent validation body with scientific knowledge. He emphasised that patient information cannot be regulated, nor provided by the pharmaceutical industry, due to conflicts of interest. Mr Rod underlined that the regulation body needs to be an independent medical organisation, adding that information influenced by bias is not what is required.

Barbara Mintzes responded that the review of the pharmaceutical directives puts a limit on the direct advertising of drugs to the public. Ms Mintzes stated that as a result the drug industries never mention the word advertising and instead use information. She added that there is no limit in law currently to public access to information. The only legal limit concerns manufacturers' ability to directly advertise their products to the public.

According to Priya Bala, there are a number of flaws in the advertising system, which she illustrated with an example in Hungary whereby GSK were fined 11, 000 Euro after they misled patients with an advertising campaign. She added that the minimal sum GSK were fined may not be commensurate with the profits the company made from advertising the drug. Such practices undermine consumer confidence that unethical information from companies is being checked.

Ivana Silva (PGEU) stressed the need to improve the provision of information to patients and the role that community pharmacists could play in this regard.

Priya Bala asserted that pharmacists, like other health professionals, are a pressure point for pharmaceutical marketing tactics. There are no guarantees for consumers that information from pharmacists is credible and not filtered through pharmaceutical marketing tactics.

Florence Vandeveld (ISDB) stressed that the only way to provide information to patients is by creating an independent regulatory body. She asserted that there is a need to regulate quality as well. Ms Vandeveld stated that any form of advertising needs to be replaced by unbiased information and questioned how companies which sell drugs can give comparative information. She concluded by emphasising that industry can not give information to patients. She stressed that the industry has replaced the acronym 'DTCA' (Direct to Consumer Advertising) with 'DTCI' (Direct to Consumer Information).

Jorgo Chatzimarkakis responded to Mr Rod by saying that although 70% of MEPs had voted against legislation in the past, there are now 70% of parliamentarians who are new to the Parliament. As a result he feels it is necessary to relaunch the debate on patient information. He suggested that articles 86 and 88 do not discuss information and that they refer only to advertising. He stated that patients are currently being misinformed, and that they should have up-to-date information which should be validated by a public authority. He stressed that a Public Private Partnership would be the way forward.

Barbara Mintzes stressed that in order to have viable information which meet the needs of public health, it is necessary to have a firewall between industry and information. She asserted that a Public Private Partnership will not work and emphasised that information needs to be totally independent of industry. In addition, she stressed the need to release all

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results of clinical trials.

Priya Bala echoed Ms Mintzes words regarding the need to publish all data from clinical trials.

Ms Ayuso Gonzalez closed the meeting and announced that the next meeting will take place on 25 October 2006 and will address Indoor Air Quality.

4. Synthesis of Gus Cairns' input to the Intergroup, European Aids Treatment Group – "A patient perspective"

Gus Cairns was due to speak at the intergroup but could not be present.

Information to patients is vital, both to save lives and improve quality of life. Information concerns not merely treatments but how to live with chronic conditions. It should include the perspectives of other patients living with the condition as well as professionals. Patients need information that is evidence-based, comprehensive, compares the risks and benefits of treatments and of no treatment, and is transparent as to source. It should be accessible to patients at different levels of experience and expertise, easy to use, in the patient's home language, and adapted to their culture.

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
- are not dependent (entirely or mainly) on funding from a single industry source
- are transparent about their sources of funding
- have clear guidelines and contractual arrangements about what the funding is for, and not for
- and whose funding is in the form of unrestricted grants which do not dictate content.

EATG feels that information provided direct to the patient by drug companies, or by patient groups dependent predominantly or entirely on a single pharmaceutical company for funding, cannot satisfy the requirements for unbiased information. Pharmaceutical companies have a conflict of interest between the needs of patients and of their shareholders. They market treatments and are therefore unlikely to have an unbiased opinion about not taking their treatment. They are unlikely and usually unable to provide information about competitor products. And, regrettably, they have a history of concealing or failing to publicise research which reflects negatively on their products.

EATG is therefore in favour of information provided by 'expert patients' which have educated themselves as intermediaries between the complex world of medicine and the needs of patients in general. But it is not in favour of information provided direct to patients by the manufacturers of treatments and other medical products.

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