Arzneimittelkommission
der deutschen Ärzteschaft
Fachausschuss der Bundesärztekammer

Opinion of the Drug Commission of the German Medical Association

on the public consultation on the
future of pharmaceuticals
for human use in Europe
of the European Commission
of 19 July 2007

Berlin (Germany), 12 October 2007

www.dcgma.org

The European Commission is seeking contributions from all stakeholders dealing with medicines for human use.[1] The Drug Commission of the German Medical Association (DCGMA) would like to take an opportunity to comment on the consultation. DCGMA is addressing the question: "*Do you see other areas than those already targeted by the Commission where regulatory action should be taken?"* and is restricting its opinion to the issue of direct-to-consumer advertising (DTCA).

Direct-to-consumer advertising (DTCA) is the consumer-directed promotion of the use of prescription drugs through newspapers, magazines, television, and internet marketing. Furthermore, pharmaceutical companies produce a range of other materials, including brochures and videos, which are distributed via multiple channels. The current Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use prohibits advertising of prescription drugs to the public. The proposed change would permit the industry direct advertising of prescription drugs for the treatment of AIDS, asthma and chronic pulmonary disorders, and diabetes.

The drug industry argues that DTCA helps 'educating' consumers about potential conditions and encourages them to see their doctor for diagnosis and treatment. While acknowledging that DTCA increases the amount spent on prescription drugs, industry argues that in the long run early diagnosis and treatment will reduce spending on other medical services, necessary in more severe cases such as hospitalization, which could be avoided with early intervention.

DCGMA agrees that patients need more information. However, DCGMA is of the opinion that patients require information about the whole range of available options, including non-pharmaceutical interventions and information on benefits and adverse effects of the different treatments, rather than promotional material.

There are examples which demonstrate that the industry's advertising overstates the benefits and understates the adverse effects and that this may be misleading. The imagery of the ads is often emotional in style while the potentially serious side effects are buried in the fine-print. Surveys reveal that people who have seen DTCA ads will often request and be prescribed the promoted drug. DTCA campaigns will usually aim to have pre-primed doctors via a parallel promotional campaign. It is to be expected that this procedure results in an inappropriately broad use of prescription drugs in cases where non-drug treatments could be considered for treatment. As a result, DTCA unnecessarily drives up the overall cost of healthcare without

[1] European Commission, Enterprise and Industry Directorate-General, Consumer Goods: The future of pharmaceuticals for human use in Europe – Making Europe a hub for safe and innovative medicines. 19 July 2007

necessarily improving the health of the patients treated with the drug. The inappropriate use of advertised drugs may even impair patients' health because of adverse effects without any chance for a benefit.

Above all, drug information should be reliable (evidence-based, up to date and transparent), comparative (presenting benefits and risks for all treatment options), and adapted to users' need (plain understandable and adapted to the patient's social, linguistic, and cultural background), and, finally it should be easily accessible.

However, the move to allow the pharmaceutical industry to disseminate information on prescription drugs directly to the patient is not an adequate way to improve drug information for patients. Pharmaceutical companies do have a dedicated role: by law, they must provide well labeled drugs, including patient information leaflets contributing to safe handling and intake of the prescribed drug, thus preventing medication errors. Industry should guarantee full transparency about properties of their products and be open to communicate new findings in appropriate ways.

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