DE KONINKLIJKE NEDERLANDSCHE MAATSCHAPPIJ TOT BEVORDERING DER GENEESKUNST IS DE ORGANISATIE VAN EN VOOR ARTSEN IN NEDERLAND

knmg

Beleid & Advies
Opleiding & Registratie
Medisch Contact & Artsennet

European Commission,
DG Enterprise & Industry, Unit F2
Pharmaceuticals
Att. Mrs. Ulla Narhi
45 Avenue d'Auderghem, Office 10/93
B-1049 Brussels

ONDERWERP
Reaction on public consultation 'Legal proposal on information to patients'

UTRECHT
7 april 2008

REFERENTIE
LMa / 08-12092

Dear Mrs Narhi,

In the paper for this public consultation, an outline is given by the European Commission, DG Enterprise & Industry of the key ideas for a legal proposal to regulate the provision of direct-to-consumers information (DTCI) on medicinal products by the pharmaceutical industry. In a report published on December 20, 2007 DG Enterprise & Industry identified as major problems in this area that there are significant inequalities between member states in access for patients and the general public to information on medicinal products and that currently the quality of information is very variable, particularly on the Internet. The overall aim of the proposals of the European Commission, DG Enterprise & Industry is to ensure that patients receive good-quality, objective, reliable and non promotional information on prescription-only medicinal products and to harmonize the existing situation in Member States in this area. Accordingly DG Enterprise & Industry proposes to uphold the ban on direct-to-consumers advertising (DTCA), but to allow for direct-to-consumer information (DTCI) by the pharmaceutical industry on prescription-only medicinal products. In order to ensure that certain quality criteria are met a national co-regulatory body (consisting of public authorities and a mix of stakeholders such as healthcare professionals, patients' organizations and the pharmaceutical industry) shall have to adopt an code of conduct on information to patients and should monitor and follow up all information activities by industry.

This reaction of the Royal Dutch Medical Association (KNMG, The Netherlands) on the public consultation contains some general reflections on the barriers in accessibility of relevant information for patients and on ways to redress this and contains critical remarks on the insufficient level of protection provided in the present proposal of DG Enterprise & Industry to patients against receiving biased, commercialized information by the pharmaceutical industry.

General reflections on barriers in access to information on medicinal products for patients and the general public
The Royal Dutch Medical Association subscribes to the need to take down unjustified barriers in access to information on medicinal products. Patients have a

KNMG
Mercatorlaan 1200
Postbus 20051
3502 LB Utrecht

TELEFOON
030-28 23 274

FAX
030-28 23 326

EMAIL
l.markenstein@fed.knmg.nl

WEBSITE
www.knmg.nl

REKENINGNUMMER
Bank 45.64.48.969

right to receive and have access to all relevant information pertaining to their health. But they are also – due to a potential lack in expertise in assessing the quality of information – susceptible to being unduly influenced by biased, commercialized information on for instance medicinal products. They have a right to be protected from such biased information. Against this background every effort should be made to improve the availability and quality of information that patients can use to improve their decision making power in matters of health care. This effort should be made by all the stakeholders involved (public authorities, health care professionals, patients' organizations and the pharmaceutical industry) in close cooperation, in order to generate information that is actually tailor made and meets the needs of patients. The pharmaceutical industry can be an interesting partner in this process because it is an important source of information on medicinal products. However, pharmaceutical industry will always have competing interests in providing patients and citizens with information and therefore any information provided by the pharmaceutical industry will always have to be scrutinized and/or adapted by an independent body. In order to fill the present gap in accessibility to good-quality, objective information on medicinal products, the Royal Dutch Medical Association would prefer further exploration of possibilities for actions involving all stakeholders to improve the present situation. As to the possibility of direct-to-consumer information by the pharmaceutical industry, the Royal Dutch Medical Association is of the opinion that such information should always be subjected to prior approval of an independent body in order to guarantee its quality.

UTRECHT
7 april 2008

REFERENTIE
LMa / 08-12092

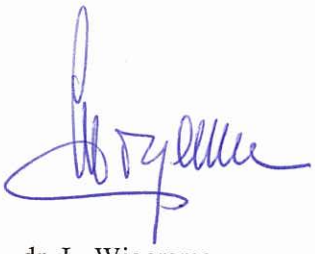
Critical remarks on the level of protection provided in the present proposal
The Royal Dutch Medical Association subscribes to the need to ensure that patients receive good-quality, objective, reliable, unbiased, patient-oriented, evidence-based, up-to-date, transparent, non promotional information on prescription-only medicinal products that is consistent with approved information. The Royal Dutch Medical Association is of the opinion that the present proposals of DG Enterprise & Industry EC for a legal framework do not contain the necessary safeguards and guarantees, because:

- The present proposals are lacking in providing for a clear distinction in what is to be considered advertising and what can be considered information. Without such a clear distinction everything is basically allowed and thus the ban on direct-to-consumer advertising (DTCA) is lifted, until – only after the fact - it is judged that it actually is advertising and/or information that does not meet quality standards. This possibility of judgment after the fact, rests with the proposed co-regulatory body which has no means of enforcing its opinions.
- The present proposals are lacking in providing for an adequate mechanism of prior assessment and/or approval of direct-to-consumer information (DTCI). This could be part of the work of a co-regulatory body and is to be considered an essential element in protecting the interests of patients.
- The present proposals suggest a distinction between 'push' and 'pull' mechanisms (and subsequent requirements) for the provision of information that is highly theoretical and therefore threatens to undermine the whole proposed framework.

knms
Beleid & Advies
Opleiding & Registratie
Medisch Contact & Artsennet

Concluding remarks
The Royal Dutch Medical Association is of the opinion that it is unwise to open up possibilities for direct-to-consumer information on medicinal products by the pharmaceutical industry without installing adequate mechanisms to guarantee the quality and objectivity of such information. We therefore do not support the present proposals by DG Enterprise & Industry. The Royal Dutch Medical Association is also of the opinion that other solutions are conceivable and should be pursued – besides direct-to-consumer information – to fill the present gap in accessibility of relevant information for patients.

Yours faithfully,



dr. L. Wigersma,
director of Policy and Advise Department
Royal Dutch Medical Association.

UTRECHT
7 april 2008

REFERENTIE
LMa / 08-12092