Statens legemiddelverk
Norwegian Medicines Agency

European Commission

ATT: Ulla.narhi@ec.europa.eu

Your reference	Date	Our reference	Archive code	Office/Officer
	04-04-2008	08/05290-1		LBOV/ Bente Jerkø

PUBLIC CONSULTATION ON A LEGAL PROPOSAL ON INFORMATION TO PATIENTS

Referring to the public consultation on key ideas of a legal proposal on in formation to patients launched on the EC website, please find the Norwegian contribution below.
The Norwegian Medicines Agency has the following comments:

- **"Pushed" information:** It is difficult to distinguish the information that is allowed from the information / advertisement that is not allowed.

- **National co-regulatory body:** This would need huge amount of resources to establish, and additional annual running costs. Experience regarding monitoring advertising and "pushed" information today indicate this. The cost would be unreasonable or excessive seen in relation to probably no improvement of public health. These resources and annual costs could be more appropriate used by increased information provided by the National Competent Authorities.

- We have to stay away from approving / monitoring "pushed" information and advertising in advance. If advertising / information have to be approved beforehand this should be a task for the EU Advisory Committee, and not for each national authority. The information would then be harmonised within Europe.

- The European commission could give some advice regarding minimum standard information provided to patients by National Competent Authorities. One way to go is to prepare guidelines for the regulations, to harmonise the information to patients on medicinal products in EU.

- Another suggestion is to make the PAR (Public Assessment Report) more suitable for patients and translate to local languages.

Norwegian Medicines Agency (NoMA)
Sven Oftedals vei 6, N-0950 Oslo, Norway
Tel: +47 22 89 77 00 www.legemiddelverket.no
Fax: +47 22 89 77 99 post@legemiddelverket.no
IBAN: NO 71 7694 05 00903
SWIFT: DNBANOKK

- These legal proposals are initiated by the pharmaceutical industry and obviously reflect their interest. Increased information provided by the pharmaceutical industry will normally represent information about medicinal products of their own interest and to increase their profit.

- Producer neutral information of medicinal products should represent one of the strategic tasks assigned to the EU Advisory Committee.
  Producer neutral information would be the only information of significant sense to improve the overall public health.

- With increased "pushed" information to the public the Pharmaceutical industry should contribute with a fixed % of their yearly expenditure devoted to promotional initiatives.

Yours sincerely
NORWEGIAN MEDICINES AGENCY

Gro Ramsten Wesenberg
Director General