

**Royal College of Nursing UK Response  
To European Commission DG Enterprise and Industry Public Consultation  
on a Legal Proposal on Information to Patients**

With a membership of over 390,000 registered nurses, midwives, health visitors, nursing students, health care assistants and nurse cadets, the Royal College of Nursing (RCN) is the voice of nursing across the UK and the largest professional union of nursing staff in the world. RCN members work in a variety of hospital and community settings in the NHS and the independent sector. The RCN promotes patient and nursing interests on a wide range of issues by working closely with the Government, the UK parliaments and other national and European political institutions, trade unions, professional bodies and voluntary organisations.

The RCN is also a member of a number of European alliances including the European Public Health Alliance (EPHA), the European Federation of Nurses Associations (EFN) and the European Federation of Public Service Unions (EPSU).

**General Remarks**

The Royal College of Nursing in the UK responded in April 2007 to a previous public discussion by DG Enterprise and Industry on the provision of information for patients on medicinal products and would like to reiterate the key points we raised in that response:

1. The RCN is opposed to the advertisement of prescription only medicines and stresses that no consideration should be given to relaxing current EU legislation on this issue.
2. There is a clear distinction between the provision of information on medicinal products and the need for general health information. These are different types of issues which should be addressed separately.
3. The RCN urges the European Commission to further investigate options to address the need of patients for more quality information on medicinal products before any decisions are made.
4. The European Commission needs to recognise the role of **Nurse Prescribers** and their role in providing information to patients on medicinal products.
5. We are deeply concerned by the lack of transparency and representation of the Pharmaceutical Forum.

**The Current Public Consultation**

Directive 2001/83/EC prohibits the advertising of prescription-only medicines to the general public whilst allowing advertising of medicines not subject to prescription. The RCN is concerned that the current proposals from DG Enterprise and Industry are watering down this legislation, particularly given the lack of clarity in the proposal on

different types of information. There is a danger that the proposals will open up to “advertising” under the banner of “disseminating information”.

The RCN supports its pan-European alliance (EPHA) in calling for a proposal that makes a clear distinction between:

information to patients  
information on medicines  
and health information.

We also support the other key elements in EPHA’s response:

- That healthcare professionals should remain the primary source of health information.
- General health information should be addressed separately from proposals governing pharmaceutical products
- The initial focus for the Commission should be on improving the level of information on prescription medicines, including the drug safety and effectiveness data provided to regulatory authorities. Given the conflict of interest for the pharmaceutical industry this information should not be provided by them.
- Any EU initiatives on provision of medicinal information should not reinforce health inequalities in terms of accessibility, clarity and sustainability.

In relation to the EU’s own processes the RCN is concerned that:

- There needs to be greater transparency and wider representation on the EU’s Pharmaceutical Forum, particularly given the use of the Forum’s conclusions by the Commission as reference for the proposed legal framework
- The Directorate General for Health in the European Commission (DG SANCO) should lead this work on patient information, and not DG Enterprise and Industry, since SANCO is the directorate with responsibility for health protection and health promotion.

In conclusion the current document requires a complete rethink with clear separation of different types of information and a lead from DG SANCO to ensure a real focus on “objective, unbiased, patient-oriented, evidence-based, up-to-date, accessible, transparent, relevant and consistent information”.

RCN March 2008

For any queries relating to this submission please contact:

International Department  
Royal College of Nursing UK  
20 Cavendish Square  
London W1M 0RG

Tel: + 44 20 7647 3598