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Registration Number  
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Brussel, 5 June 2006

TO: European Commission  
DG Enterprise and Industry/F2  
Pharmaceuticals

Dear Mr. Arlett,

The European Federation of Nurses Associations would like to thank you for the invitation to the constructive and informative workshop which took place on 20 April 2006. Based on the open dialog with the Commission and stakeholders (except Industry) present, and after internal consultation, EFN provides its input to the Commission Public Consultation on "An Assessment of the Community System of Pharmacovigilance"

**Name: European Federation of Nursing Associations – EFN  
Clos du Parnasse 11 A  
1050 Brussels**

**Type of stakeholder: healthcare professionals**

**Organisation: Pan European Organisation, representing National Nursing Associations from 30 Member States**

Although your DG and in specific Unit F2 focuses only on Pharmacovigilance, EFN believes that steps further in the process of EU legislation and National legislation are only possible if the overall concerns about patient safety are taken into account. It is essential to establish a culture of safety throughout the entire health system, so that all actors in the system become aware of where, when and how to avoid errors and adverse events. The development of this safety culture, in which staff and patients work together to generate knowledge and evidence based practice that prevent errors and adverse events, will be of benefit not only to countries in the European Union but also to the rest of the world.

The complexity of health systems calls for improved communication, coordination, continuity, education and management and the increased use of new technology. This depends on staff working in the health sector having skills and knowledge in these areas.



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Based on the definition used by the Commission on Pharmacovigilance, EFN provides you with concrete actions and reflection to improve the current system:

- **Collecting data** on the safety of medicines: From a nursing perspective, Pharmacovigilance is about observations and reporting, two key components in the process of nursing care. EFN believes that errors and adverse events are communicated to all those working in the health care system through a culture of open learning and not through a culture of “name and shame”. Governments, health organisations and senior managers need to take responsibility for developing this safety culture. Throughout Europe, nurses are the largest occupational group in the health care sector, providing the majority of direct patient (24 hours on 24 hours) and client care in a wide range of settings including primary health care, acute general and psychiatric hospitals as well as long-term hospitals and nursing homes. Nurses working conditions are difficult and many actors in the health systems are asking data. The frontline workers need to provide these data but we need to make sure that the nursing care process, the quality of care delivery, will not be put into danger. Flexible, user friendly technology needs to be provided to the nurses, in all settings, to collect data on patient safety. Nowadays more than 45% of nurses work is paperwork which keeps the nurse away from the bedside. In Annex 1 we add the Royal College input to the consultation.
- **Managing data** on the safety of medicines and looking at the data to detect ‘signals’. A datawarehouse on Patient Safety, with comparable indicators need to be build at National and European Level. It is of significant importance that the aggregated data are communicated to the nurses who collected the data so incentives are build in to motivate the nursing workforce. If there is no feedback, it is difficult to convince nurses to keep on collecting data.
- **Evaluating the data and making decisions** with regard to safety issues: National Nursing Associations need to be involved in the decision making process. Exchange of information and research with other EU countries is of significant importance and the High Level Reflection Process is a best practice example where Member States and NGOs meet to exchange experiences.
- **Acting to protect public health:** The complexity of health systems calls for improved communication, coordination, continuity, education and management and the increased use of new technology. Effective information and education in health enable patients to take on more responsibility for the management of their disease or condition. It helps patients to maintain their independence and can lead to better health outcomes. All patients have a right to access to clear and accurate information about their health, health problems, and choice of care. Patients require different types of information, presented in different forms depending on literacy and educational levels, and cultural and social needs.



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Empowerment of patients depends partly on patients having sufficient information to understand their condition, choice of treatment and care, changing needs, and future sources of information. Health professionals should respect the choices patients make under these conditions and assist them to carry out these choices.

Nurses are an important influence on the individual patient's experiences of health care and in achieving change and implementation. Patient safety needs to be promoted at all stages of quality assurance and in every aspect of the care and treatment of patients. In order to strengthen the Community pharmacovigilance system, we need to make sure that a 'good health care service' is based on evidence-based research. The quality of services and its contribution to the promotion of public health is a health indicator next to morbidity and mortality rates. By doing this, the EU will be able to establish binding and non-binding cross-European standards in health care. Furthermore, in order to protect and promote a high level of public health and safety of patients, consumers and health care workers, EFN calls on to strengthen patient's rights is the key element in Europe future legislation. Addressing people's rights and changing needs are a significant advocacy role of nurses.

- **Communicating with stakeholders:** The G10 is an example how it shouldn't work. Health care professions, or at least one representative for all, were not around the decision making table of the G10. It is important to strengthening NGOs capacities to fully participate in future health policy. NGOs have a very important contribution to make in EU policy making and programmes. Therefore, EFN promotes the participative status of INGOs of the Council of Europe (see Junger Report). EFN is taking the lead in the Health grouping of the INGO Council of Europe, bringing together more than 75 NGOs interested in Health. Working together is much more than defending your own position. Within the social dialog and the European Social Model, it is of significant importance to define roles, responsibilities and accountability.
- **Audit,** both of the outcomes of action taken and of the key processes involved: As only Regulatory bodies and Industry are the key stakeholders in the legislation on Pharmacovigilance, EFN believes that Health Care Professionals and Patients Organisations are the key partners for external audits.

We would like to underline that the nursing perspective more than only observations and reporting, as the evidence indicates that most drug errors occur as a result of poor communication either verbal or written, inadequate patient assessment, staffing shortages, procedural compliance i.e. not adhering to policies and protocols.



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Standards, data, guidelines, national EU safety agreed outcomes/goals, education, risk management are required and there is also a need to create a culture of error reporting, risk reduction and steps to prevent reoccurrence and minimize individual blame or retribution for staff.

Finally, we would like to conclude that the spirit of former Commissioner Byrne policy making process 'investing in health' is the key for success. It is important to introduce incentives for Member States in developing innovative approaches to health care policy and to evaluate the efficiency and cost-effectiveness of products and services in health care. By doing this the future of Europe will guarantee the compatibility between social European policy and the free market principles which are already introduced by EU legislation into health and health care.

We hope this input from the nurses supports your DG in policy making and we are looking forward to the outcomes of the consultation process.

Best Regards,

Paul De Raeve  
Secretary General  
EFN





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## Annex 1 – Royal College of Nurses Input

### European Federation of Nurses Associations response to the European Commission

#### Consultation on “An Assessment of the Community System of Pharmacovigilance”

1. Reporting of Adverse Drug Reactions (ADRs) – there are many ways that people can report these ADRs in the UK. Yellow card reporting is the most common, and something that until recently only Drs and Pharmacists could do. This was then extended to Nurses a few years ago – and now has been opened up to the public, so that they are able to directly report themselves.
2. I believe that this opening up of the yellow card reporting scheme has seen an increase in ADR reporting.
3. Methods of reporting include “Yellow Cards” which appear in our National Formularies (BNF, NPF, MIMS & MIMS for Nurse). The yellow card scheme has also been possible within the last year online – see link below  
[http://www.mhra.gov.uk/home/idcplg?IdcService=SS\\_GET\\_PAGE&nodId=287](http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodId=287)
4. It was estimated in a recent UK Parliamentary Health Select Committee – that only 10% of all ADRs are actually reported to the Medicines and Healthcare Products Regulatory Agency (MHRA) – and the option of making this reporting compulsory has been voiced.
5. The compulsory reporting of ADRs would have an effect on the amount of data received, and therefore future patient safety. This is something which I personally believe should be a statutory duty for healthcare professionals.
6. Some UK medics in the nursing press – when interviewed on this subject have asked for payment for their services for this reporting!! The RCN view would be that patient safety should not be reliant on payment for reporting.
7. In relation to Drug errors as opposed to ADRs, the National Patient Safety Agency (NPSA) rolled out its National Reporting and Learning System (NRLS) across the NHS during 2004. In the future NHS staff anywhere in England and Wales can now report patient safety incidents, including prevented patient safety incidents (known as near misses), that they are involved in or witness. This is available on the website link below:  
<http://www.npsa.nhs.uk/health/reporting/reportanincident>
8. Members of the public who want to report a patient safety problem can call the NPSA freephone telephone number – 0800 0152536.
9. Reports sent to the NPSA will be held in an anonymous format and used to help the NPSA identify trends and patterns in patient safety. These reports will also help the NPSA to provide solutions to patient safety issues. This no blame culture is at the heart of what this organisation is trying to achieve – i.e. learn from mistakes – not punish.