**Template for responses (DEADLINE end of May 2006 responses should be e-mailed to peter.arlett@cec.eu.int)**

RESPONSE TO: Commission Public Consultation: As Assessment of the Community System of Pharmacovigilance

**Name:** The Danish Medicines Agency

**Type of stakeholder (e.g. patient/ healthcare professional/ regulator/ industry): Organisation (e.g. European patient group or National industry association - if relevant):** National Competent Authority

**Your comments:**

**General:** On the 11nd of January 2006, the Danish Medicines Agency submitted its initial comments to the draft final Fraunhofer Report. Please find below our additional comments to the EU Commission's Public Consultation of the Assessment of the Community System of Pharmacovigilance.

The effectiveness of the EU Community System of Pharmacovigilance is of outmost importance to all stakeholders within the EU Medicines Network. Denmark supports the maintainance and constant evaluation of a European system to collect and evaluate pharmacovigilance data. Therefore, Denmark supports the efforts of the EU Commission to strengthen the existing European pharmacovigilance system. In particular, we support enhanced focus on the below mentioned areas:

**1. Data sources and safety issue detection**
A major task is to encourage European Health Professionals to improve the number of ADRs and to ensure that the quality of the ADRs submitted is sufficient high. In parallel, it should be considered how consumers could be more pro-active in providing inputs on ADRs to the relevant authorities. Experiences on how to collect data from Health Professionals and consumers could be obtained from Member States with such experiences and "best practices" could be developed. This piece of information could serve as a valuable basis ensuring further scientific evaluation and consistency of ADRs´ detection in Europe.

**2. Legal framework, new legal tools and further collaboration**
Denmark strongly supports to enhance European and international collaboration in this field. A cornerstone in this respect is the work leading hopefully to the successful final implementation of the European Risk Management Strategy (ERMS). Recognizing, that the ERMS evidently is in constantly development, Denmark cannot exclude that in the future the legal framework or new legal tools are necessary in order to make sure that Europe has a safe and well-functioning pharmacovigilance system. However, at present, it is to premature, to decide the form and content of any such new initiatives.

Denmark would like to stress that we consider that international co-operation on pharmacovigilance data is of outmost importanc. Therefore, we urge the EU Commission to

finalise any bilateral agreements with third countries that ensures the legal certainty regarding the exchange of data and information between the EU, EMEA and Member States.

**3. Decision making in pharmacovigilanc**e
One important step in order to ensure the easy flow of information on pharmacovigilance within the EU is to enhance and facilitate the communication between the different European Committees and Working Groups dealing with pharmacovigilance and other regulatory issues. Denmark suggests that in order to speed up the flow of information, as a first step, one should support the present work undertaken by the European Medicines Network looking at ways on how to facilitate co-operation between CHMP and PhVWP and the NCAs.

**4. Impact of communications and action**s
Denmark considers that the European Medicines Network could share knowledge about the actual pharmacovigilance situation within Europe today in a more effecient manner. As stressed before, one way to do this is to search for ”best practices” within the Member States. Beyond the already mentioned enhanced co-operation between the different Committees and Working Groups, the EU should look at how to utilize existing drug databases more effectively from a pharmacovigilance perspective.

**5. Additional comments**
Development of a sound European pharmacovigilance system is pivotal. However, any such system does not exist indepentently of other aspects of the EU Medicines system. Therefore, Denmark suggests that a solid European pharmacovigilance system should be complemented by other essential risk/benefit initiatives linked to the approval and safety of medicines.

One important area is to move up the level of scientific evidence to the highest possible level. The EU should work for the implementation of an even more comprehensive scientific coordinated response based on a purely scientific solid European recognised evaluation. Support of PSUR-worksharing between the National Competent Authorities may be the basis for reaching further progress. In addition, harmonisation of birthdates in accordance with the recent agreement reached within the Heads of Medicines Agencies, HMA, may be followed up by new EU legislative initiatives. Another important area is to support funding of new research initiatives and programmes developed to minimize the risks of pharmacovigilance in medicinal products.

The role of individual companies is also of significant importance. Companies must recognise the responsibility they have in making solid risk/benefit assessments of their products. They must also inform the relevant authorities immediately whenever there are problems with any of their products. Companies with an ”open approach” to this issue should be invited to discuss this matter further at an European level. Stakeholder dialogue in this respect is the way forward.

29 May 2006,
On behalf of the Danish Medicines Agency

Jytte Lyngvig
Chief Executive Director