Wyeth

15 October 2008

European Commission
Enterprise and Industry, Directorate-General
Pharmaceuticals Unit
B-1049 Brussels

Dear Sir or Madame:

Wyeth Pharmaceuticals is pleased to have the opportunity to provide comments on the Public Consultation Paper entitled, "*Draft list of fields contained in the 'EudraCT' clinical trials database to be included in the EudraPharm' database on medicinal products and made public, in accordance with Article 57(2) of Regulation (EC) No 726/2004*".

Wyeth is one of the world's largest research-based pharmaceutical and healthcare products companies and is a leading developer, manufacturer and marketer of prescription drugs, biopharmaceuticals, vaccines, and over the counter medications. As such, Wyeth understands the importance of clinical trial transparency to public health and appreciates the opportunity to comment and provide our perspectives on the proposed clinical trial information to be made publicly available in the EudraPharm database.

As a general comment, it is our view that providing much of the highly-detailed, scientifically-oriented data proposed within the Public Consultation Paper will not be of interest or benefit to the public. Providing data on the biological origin, the origin of cells, or even the orphan drug designation number will be of limited value and potentially confusing to the general public. Likewise, descriptive details regarding a clinical trial that include MedDRA versions and levels, pharmacogenetic / pharmacogenomic / pharmacoeconomic information, and much of the proposed trial design information will be of limited value to the general public and runs counter to the intent that the information presented be meaningful for the public. We recommend that the Directorate-General limit the product and clinical trial information to basic, descriptive data that is relevant to a lay audience.

Wyeth

We appreciate the opportunity to comment on the above-referenced Public Consultation Paper, and trust that the European Commission will find our comments helpful and constructive in developing a set of data elements that will provide meaningful clinical trial information to the public.

Sincerely,

Roy Baranello
Assistant Vice President
Global Regulatory Policy and Intelligence
Wyeth Pharmaceuticals