Communication from the Commission regarding the guideline on the data fields contained in the clinical trials database provided for in Article 11 of Directive 2001/20/EC to be included in the database on medicinal products provided for in Article 57 of Regulation (EC) No 726/2004

(2008/C 168/02)

1. INTRODUCTION

Article 57 of Regulation (EC) No 726/2004 ([1]) provides for the European Medicines Agency to establish a database on medicinal products authorised in the Community to be accessible to the general public — the so-called EudraPharm database ([2]). This provision also stipulates that, where appropriate, the database shall also include references to data on clinical trials currently being carried out or already completed, contained in the clinical trials database provided for in Article 11 of Directive 2001/20/EC ([3]) — the so-called EudraCT database ([4]).

The same provision requires that the Commission issues guidelines on the clinical trials data fields which could be included and which may be accessible to the public, by identifying the data fields from the clinical trials database corresponding to the information that may be included in EudraPharm.

This information is of potential value to patients, their carers and the health professions, who have a potential interest in ongoing or completed trials. At the same time, more transparent information can contribute to the development of further research helping to ensure that better trials are designed, requiring fewer patients and avoiding unnecessary duplication. The pharmaceutical industry, academia and the scientific community and regulators are other potential users of this type of information.

The EudraCT database includes clinical trials on medicinal products for human use, with at least one site in the Community, and which commenced in at least one Member State following the transposition of Directive 2001/20/EC. Clinical trials commencing prior to that point and clinical trials with no site in the Community are not included in EudraCT and cannot therefore be referenced by EudraPharm (except for those third country paediatric clinical trials that are included in a Paediatric Investigation Plan in accordance with Regulation (EC) No 1901/2006. Publication of information on paediatric clinical trials is to be the subject of a separate guideline).

The purpose of this guideline is to identify the data elements from the EudraCT database corresponding to the information to be included in EudraPharm, to identify the trials which will be included and to set out the criteria for the update of this data. The overall purpose is to provide relevant information to the public in the interests of public health.

At the time of publication of this guideline the EudraCT data fields are for the most part consistent with international initiatives relating to clinical trial registries, e.g. WHO International Clinical Trials Registry Platform (ICTRP) and the International Committee of Medical Journal Editors (ICMJE). Although EudraCT may have additional fields, the convergence of the information to be made public with the WHO ICTRP facilitates the work of sponsors and researchers submitting information to different registries for different purposes, and facilitates the access of patients, health professionals and citizens in general to this information.

2. DEFINITIONS

Applicable definitions will be those contained in Directive 2001/83/EC and Directive 2001/20/EC.

3. SCOPE

Taking into consideration that the EudraCT database is only accessible to the competent authorities of the Member States and the European Medicines Agency in order to ensure that the confidentiality of the data is strictly observed and to protect the legitimate interests of sponsors, the information to be made publicly available keeps the balance between this principle and the need to inform the public in the interests of public health and transparency.

With these objectives in mind the information to be made available needs to be meaningful for the public, also by following agreed standards at international level. Moreover, phase I trials, certain details of the characterisation of the investigational medicinal products, certain details of the clinical trial design, information on batch release aspects, legal status of the sponsor, clinical trial sites and any personal related information are excluded from publication.

The information referred to in Section 4 to be included in the EudraPharm database shall cover clinical trials of phases II, III and IV, regardless of whether the medicinal product concerned has already received a marketing authorisation in the Community or not.

Each clinical trial will be listed as 'ongoing' or 'ended'. This status will be listed for each Member State with the relevant dates.

Clinical trials which have received a decision from the Competent Authority and/or a favourable opinion from the Ethics Committee, in the Member State in question, will be identified in the EudraPharm database. Once the clinical trial has been approved it will be listed as 'ongoing'. This listing will change to 'ended' once the clinical trial has been registered as ended in EudraCT.

([1]) OJ L 136, 30.4.2004, p. 1.
([2]) http://eudrapharm.eu
([3]) OJ L 121, 1.5.2001, p. 34.
([4]) http://eudract.emea.europa.eu

4. INFORMATION ELEMENTS TO BE INCLUDED IN THE EUDRAPHARM DATABASE

The information to be published in the EudraPharm database will consist of data fields on the clinical trial including the following elements:

(a) Identification of the clinical trial and the sponsor:

- EudraCT number for the clinical trial,
- sponsor's designation and protocol code number,
- full title of the trial,
- the International Randomised Standard Clinical Trial Number (IRSCTN) where available in EudraCT,
- other international identifier(s) to be defined,
- contact point(s) for further information.

(b) Identification of the medicinal product:

The medicinal product will be identified by as much of the following that is available in EudraCT (the nature of the clinical trial may mean that some items are not present in EudraCT):

- name of the medicinal product,
- active substance(s),
- route of administration,
- therapeutic classification code,
- appropriate international identifiers.

(c) Identification of the indication under study in the clinical trial and of orphan designation:

The indication(s) will be described in accordance with the agreed international terminology at the level used in the clinical trial application.

Where a product has been designated as an orphan medicinal product for the indication under study this will be indicated and the designation number provided.

(d) General descriptive information on the clinical trial and the patient population included:

- major objective,
- principal inclusion and exclusion criteria of the clinical trial,
- phase of the clinical trial,
- design (e.g. randomised, controlled),
- comparators (medicines/other treatments) if this is part of the clinical trial,
- number of patients anticipated in the clinical trial,
- age range(s),
- gender.

Taking in consideration the ongoing developments of the EudraCT database, as a result of international convergence and the implementation of Regulation (EC) No 1901/2006, publication of clinical trial results, both positive and negative, will be included as the information becomes available on the database and will need to be provided in accordance with the guidance on the clinical trial application form and the declaration of the end of a clinical trial form, as published by DG ENTR in Volume 10 of EudraLex ([1]).

5. GUIDANCE ON IMPLEMENTATION

A glossary will be provided in an appropriate location on the database website, explaining the relevant technical and regulatory terms and acronyms for the benefit of the general public.

DG Enterprise and Industry will publish detailed data elements corresponding to the information that is to be included in EudraPharm.

The actual physical and logical data models to be used in implementing this guideline will be drawn up through object modelling. Other functionalities will have to be defined by technical specifications to be prepared when this guideline is implemented.

([1]) http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev10.htm