EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Mr. Stefan Fuhring
Public Health Directorate-General
European Commission
B-1049 Brussels
BELGIUM

21 September 2010
Doc. Ref. EMA/582926/2010

Dear Mr. Fuhring,

Subject: European Commission public consultation on the "Draft detailed guidance on the collection, verification and presentation of adverse reaction reports arising from clinical trials on medicinal products for human use ('CT3')"

1. EudraVigilance Expert Working Group comments

Please find attached the consolidated comments from the EudraVigilance Expert Working Group (EV-EWG) in relation to the public consultation on the revised guidance CT3.

2. European Medicines Agency Comments

The Clinical Trial Facilitation Group (CTFG) submitted on 18 June 2010 a document highlighting the core functionalities it considers as a prerequisite for a fully operational EudraVigilance Clinical Trial Module (EVCTM). This document was prepared to outline in further detail the CTFG's understanding as how the overall requirements listed in chapter 6.2 'Basic functionalities' and 6.3 'Enhanced functionalities' of the draft CT3 guidance should be implemented.

In this context, the European Medicines Agency (the Agency) would like to suggest removing the list of functional EVCTM requirements from chapter 6 of the draft guidance CT3. Instead, as proposed in point 9.3 of the EV-EWG comments document, the detailed functional specifications for EVCTM should be drawn up by the Agency in collaboration with the Member States and the European Commission together with a timeframe for their implementation. The EVCTM requirements should consequently be addressed in the form of a technical requirements document and implementation plan and not in the CT3 guidance as such.

3. Cost Assessment of EVTCM Enhancements

The Information and Communications Technology Unit has conducted a cost assessment of the enhanced functionalities as described in chapter 6.3 of the draft CT 3 guidance taking into account the further specifications as provided by the CTFG on 18 June 2010.

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Overall, the requirements for the extended functionalities for EVCTM represent a set of features that are broadly similar to those envisaged for authorised medicinal products in the context of the implementation of the new pharmacovigilance legislation. Much of the necessary work in relation to required infrastructural changes is envisaged in the Agency's draft medium term planning for EudraVigilance, EudraCT, the Eudra Data Warehouse and the EU Telematics Controlled Terms (EUTCT) systems. Should the assumptions underpinning that planning as represented in the EU Telematics Plan hold, particularly as regards availability of funding and the timing of development within the various inter-dependent systems, then the required functionality could be implemented during 2013 and be available in 2014. The cost of implementing the proposed functionality comprises additions to the system as already envisaged. Accordingly, the additional cost of implementation is restricted to the creation of additional Analysis Reports in the EudraVigilance Data Warehouse and Analysis System and the incorporation of alerting mechanisms. Preliminary estimates indicate an additional cost of not less than €600,000, to what is already programmed.

Should implementation earlier than described above be required, the Agency will need to put in place the infrastructural elements earlier. This may result in higher costs across the programme over time as requirements may need to be re-worked because of the change in the order of implementation. In addition, parts of the programme planned for the next 18 months may have to be deferred to permit this work to be undertaken.

The Agency is examining the option of putting into place some temporary technical arrangements to meet some of the needs in the short term. It is anticipated, that making available lists of investigational medicinal products or substances to sponsors making clinical trial applications to EudraCT could be put into place in 2011 to satisfy a subset of the requirements outlined in the draft detailed guidance. However, this too, is subject to the identification of budget which is not currently allocated for this purpose.

It should also be mentioned that this cost assessment does not yet take into account the requirements described in point 12 of the comments of the EV-EWG. This refers to a proposal for a central EU electronic repository for Development Safety Update Reports (DSURs) and a tracking system for Development International Birth Dates (DIBDs). However, similar functionalities will be developed in the context of the new pharmacovigilance legislation for the Community Reference Date and the Periodic Safety Update Reports and once established, could be extended to DSURs and DIBDs.

In conclusion, the Agency would like to emphasize that taking into account the current budgetary situation the highest priority would need to be given to deliver all new EudraVigilance functionalities that are required for a successful implementation of the new pharmacovigilance legislation. This refers specifically to the need to pass the independent audit on EudraVigilance in line with the functional specifications, which are to be drafted by the Agency, the Member States and the European Commission.

I hope that the above will provide you with a useful input from the EV-EWG and the Agency in response to the public consultation on the draft CT3 guidance. If you require further information, please do not hesitate to contact me.

Yours sincerely,

Noël Wathion

Head of Unit Patient Health Protection
European Medicines Agency