EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation
Medicines: policy, authorisation and monitoring

PHARM 721

PHARMACEUTICAL COMMITTEE
18 October 2016

Subject: **Implementation of the Clinical Trials Regulation**

Agenda item 2ii

Update from European Medicines Agency (EMA)

Progress on the development of the EU Clinical Trials Portal and Database

- According to the timelines adopted by the EMA Management Board in December 2015 the audit of the CT Portal and Database will be carried out in August 2017 and will be completed by November 2017 with the Regulation becoming applicable in October 2018. The current timelines are the maximum timelines; all efforts for earlier application are to be made to bring the Regulation into application as soon as possible.
- There will be an audit release as well as a production release of the system. The latter will be in time for National Competent Authorities (NCAs) to familiarise themselves with the system.
- A number of discussions were held with Member States on the auditable business requirements for the EU Portal and Database. These discussions are now finalised.
- The development is progressing and currently the system includes functionalities covering the creation and submission of initial Clinical Trial Application, selection of Reporting Member State and initiation of assessment process.
- User acceptance testing (UAT) takes place following each iteration of the system (approximately every 12 weeks). Representatives from the Member States (NCAs and Ethics Committees) and from the sponsors, including both pharmaceutical companies and academia, are involved in the UAT. The EMA has conducted three UATs – UAT 1 took place in March, UAT2 in June and UAT3 in September. Feedback from UAT1 and UAT2 has been incorporated in the system.

- Work on the Member States Application Programming Interface (API) is progressing. 4 additional workshops will be held with a restricted group from MSs between Sep 2016 and Jan 2017. The workshops will focus on:
    - Define and agree the scope of the API based on the approved requirements
    - Define the details (e.g. security, authorisation, entity representation)
    - Finalise the specification

  A workshop with the IT directors will be held in Jan 2017 to present the API specifications

Update from the Commission

Collaboration of Member States with EMA and COM

The application of the new CT Regulation has to take place as soon as possible.

COM cannot emphasise enough the importance of keeping with the maximum timeline of October 2018 agreed during the December 2015 EMA Management Board meeting for the application of the Clinical Trial Regulation.

In this respect we urge Member States to collaborate constructively with EMA and COM to advance further on the development of the EU CT portal and database to ensure that the IT system is simple and clear in line with the requirements of the Clinical Trial Regulation. In order not to delay further the application of the Regulation it is necessary to avoid repeated discussions on the same topics in various fora.

Additionally MS should ensure that the necessary arrangements, (such as organisation at national level of National Competent authorities and ethics committees to ensure timelines and/or procedures of the Regulation, update of national legislation and fees, and development of a national IT system) are put in place within the same timelines to ensure the effective implementation of the Regulation.

Any further delay in the project is not admissible. There is a huge pressure from the public and the stakeholders (and the EP) to have in place as soon as possible the new legislation, one of whose key objectives is to strengthen the attractiveness of the European clinical trial environment, benefit researchers and patients in Europe and foster innovation. The reputational risk of the EU is at stake.

Progress on Legal obligations

The work on the legal obligations related to the Clinical Trial Regulation No 536/2014 is ongoing and is on track. The status of the technical documents is as follows:

• Commission Implementing Act on detailed arrangement for clinical trials inspection procedures including the qualifications and training requirements for inspectors (Article 78(7)) – is currently undergoing a second public consultation for 1 month until the end of October. The next step is consultation of the Standing Committee through written procedure and we aim for adoption by the end of 2016.

• Commission Delegated Act on principles and guidelines on good manufacturing practices for investigational medicinal products for human use and inspection procedures (Article 63(1)) – is currently undergoing an internal consultation in the Commission. This

will be followed by a second public consultation for 1 month which will be launched November 2016. Between December 2016 and March 2017 the document will undergo the scrutiny by Council and European Parliament and adoption in April 2017.

Following consultation with the ad hoc group on clinical trials in Q2 2016 regarding the "Detailed Commission guidelines on good manufacturing practices for investigational medicinal products" (Article 63(1)) we will be consulting the pharmaceutical committee through written procedure in October. Between October and December 2016 there will be the Commission internal and decision procedures and publication in April 2017.

Progress on new guidelines and revision of existing ones

The public consultations on the following four guidelines ended on 31 August 2016:

1. Risk proportionate approaches in clinical trials
2. Summary of Clinical Trial Results for Laypersons
3. Definition of Investigational Medicinal Products (IMPs) and use of Auxiliary Medicinal Products (AMPs)
4. Ethical Considerations for Clinical Trials on Medicinal products conducted with Minors

The comments received were forwarded to the relevant task group of the ad hoc group on clinical trials. Once the comments are reviewed by the task group and the document is updated as necessary, it will be sent to the ad hoc group for a final consultation. We aim to publish the final version by the end of 2016 / beginning 2017.

A meeting was held (in June 2016) with the *ad hoc* group on clinical trials (CT), established under Directive 2001/20/EC which has been renamed as "expert group on clinical trials". Discussions included:

- the practical functioning of the transitional period provided for by the Clinical Trial Regulation.
- data protection issues in the CTR in light of the recently adopted Regulation on Data Protection

The next meeting is planned to be held on 14 December 2016.

Action to be taken:
For information