EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Focus Group: a better system to navigate guidelines on ATMPs

Objectives of the Focus Group and outcome of discussions in 2011

CAT Stakeholders workshop 12 January 2012

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MEEETING OF THE FOCUS GROUP IN MAY 2011

Participants: CAT, GTWP, CPWP experts, CAT interested parties (EUROPABIO, EBE, EUCOMED, Clinigene, EATRIS), CAT/WPs secretariats, EMA regulatory affairs

Objectives of the meeting:

-Brainstorming: how to improve the system by which developers can navigate the maze of ATMPs guidance documents.

-Collection of significant points highlighted by interested parties (reported to CAT in June 2011).

-Proposed actions (adopted by CAT in July 2011)

Brainstorming: how to improve the system by which developers can navigate the maze of ATMPs guidance documents (1/2)

List of guidance documents applicable to GTMPs discussed as case study. Noted that guidelines are published in different web pages on the EMA website: information not easily accessible by developers.

Content of specific ATMP guidance documents. IPs highlighted that guidance documents are highly appreciated when give clear directions to developers, hence enhancing predictability of regulatory outcome. Guidance documents applicable to specific category of products should provide additional information rather that duplicating what is already contained in general guidelines.

Brainstorming: how to improve the system by which developers can navigate the maze of ATMPs guidance documents (2/2)

Some guidance documents are written from the perspective of the marketing authorisation: other stages in the product development should be looked after

IPs highlighted that from the point of view of developers, all guidance documents are perceived as having the same value in terms of their applicability, even if they are reflection papers

Collection of significant points highlighted by interested parties (reported to CAT in June 2011) (1/2)

Proposal to consolidate all guidance documents applicable to gene therapy products in one document: most IPs felt that this would be difficult to navigate and to maintain. Proposed an interactive flowchart hyper-linking all applicable documents.

Proposed flowchart to take into account the different lifecycle phases (development/pre-MAA, MAA, post-authorisation) and features (quality, pre-clinical, clinical). To gradually guide the applicant from general to product-specific guidances (presented later today)

Collection of significant points highlighted by interested parties (reported to CAT in June 2011) (2/2)

Question and Answers document are generally very useful and easier to be updated.

ATMP webpage is not easily accessible: banner not available on the homepage, 'quick-link' to Advanced Therapies is hidden, The current section on ATMP guidelines is also not linked to the other scientific guidelines. Proposal for short explanatory document/page to explain how to navigate the EMA's website.

It would be helpful for developers to find in scientific advice letters the references to the applicable guidelines.

Proposed actions (adopted by CAT in July 2011) (1/2)

- To work on an interactive flowchart
- To revisit available guidance documents and explore possibility to merge existing guidelines when the content is overlapping
- CPWP to perform horizon scanning on available guidance and produce a list of guidance documents applicable to cell-based medicinal products and a gap analysis of what is missing
- To understand how guidance documents are interpreted at national level by NCAs. Academia representatives and National Funding Research Organisations to be engaged in this dialogue

Proposed actions (adopted by CAT in July 2011) (2/2)

- To explore ways to improve navigation of EMA web pages on ATMPs
- To publish on ATMP web pages links to useful publications (e.g. scientific papers published by CAT, other documents that can inform on EU validated/approved biomarkers)
- IPs to provide input on specific areas where further guidance is needed
- To report to the relevant WPs the proposal to include more references to applicable guidelines in scientific advice letters

THANKS FOR YOUR ATTENTION!