European Medicines Agency
Inspections

London, 14 July 2008
Doc. Ref. EMEA/INS/GMP/372447/2008

GMP for Advanced Therapy Medicinal Products: Status

Article 5 of Regulation (EC) No. 1394/2007 states that "The Commission shall, after consulting the Agency, draw up guidelines in line with the principles of good manufacturing practice and specific to advanced therapy medicinal products."

EMEA receives a number of enquiries about progress with the above guidelines. It appears that there is a public perception anticipating the development of extensive new GMP requirements for advanced therapy medicinal products. Existing GMP guidelines interpreting the principles laid down in Directive 2003/94/EC are already quite extensive and already applicable to these types of product.

Nevertheless, well before the adoption of Regulation (EC) No. 1394/2007 the need for some work in this area was first identified. EMEA published a concept paper in December 2003 on GMP for gene therapy and somatic cell therapy products. This work was subsequently incorporated into a revision of Annex 2 of the GMP Guide as mentioned in a further Concept Paper published in May 2005. It is intended that Annex 2 will provide supplementary GMP guidance on all biological medicinal products with the exception, at least for the time being, of medicinal products derived from human blood or plasma, which are already subject to a specific GMP Annex (Annex 14). This annex is also undergoing revision in view of the new regulatory framework for the collection and testing of blood introduced by Directive 2002/98/EC. A Concept Paper was published in March 2005.

A draft of the revised Annex 2 was published for consultation in September 2007. The deadline for comments was 14 March 2008. The new draft annex introduces general supplementary guidance applicable to all biological medicinal products followed by supplementary guidance specific to certain types of biological medicinal product. At the time of publishing it was noted that while sections on gene therapy and cell therapy medicinal products existed, no specific guidance on tissue engineered medicinal products had been developed. Particular attention was drawn to this omission at the start of the public consultation and comments invited.

The public comments are under consideration and the drafting group has been enlarged to include a broader range of expertise. It is expected that a final text will be transmitted to the Commission towards the end of this year and published shortly afterwards. Although a large number of comments were received during the public consultation (in excess of 700 comments from 29 sources) there were no comments relating specifically to tissue engineered products. The drafting group believes that the GMP-related aspects for this group of products are closely related to those for cell therapy products and therefore it is anticipated that they will be dealt with together rather than separately in the new Annex.

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