Celyad

September 23, 2016

Submission of Comments on the Consultation Document:
Good Manufacturing Practice for Advanced Therapy Medicinal Products

Celyad is happy to respond to the Commission Consultation on Good Manufacturing Practice (GMP) for Advanced Therapy Medicinal Products (ATMPs).

Celyad is a clinical-stage biopharmaceutical company focused on the development of specialised cell-based therapies. The Company utilizes its expertise in cell engineering to target severe diseases with significant unmet need, including cancer. Celyad's Natural Killer Receptor based T-Cell (NKR-T) platform has the potential to treat a broad range of solid and liquid tumours. Its lead oncology candidate, NKR-2, is currently being evaluated in a Phase I clinical trial. In addition, Celyad has completed a Phase III trial in the EU for its C-Cure® cardiovascular disease candidate in chronic ischemic heart failure. Celyad was founded in 2007 and is based in Mont-Saint-Guibert, Belgium.

Celyad welcomes the initiative of the European Commission and in particular the openness of the Commission to envisage greater flexibility in applying GMP for ATMPs taking into account their specific characteristics. The new Consultation Document has been significantly expanded compared to last year Consultation Document and we have noticed several of our proposed changes have been incorporated (including the ones related to the preparation/reconstitution of cryopreserved products at the administration site), for which we are very grateful.

Celyad is an SME (EMA/SME/165/12/R3), member of organisations such as the Alliance for Regenerative Medicine (ARM), Co-ACT or bio.be, the Belgian national biotech organisation, part of EuropaBio, and has interacted with these organisations in the context of this consultation.

Celyad generally supports the comments provided by ARM and EuropaBio.
More specifically, Celyad considers the following elements as particularly important to address in order to facilitate the development and deployment of ATMPs in Europe:

- GMP for ATMPs should not be a stand-alone document but should be incorporated as an annex to the Volume 4 of EudraLex. Several key aspects of GMP are missing or insufficiently developed in the consultation document. Completing this document to meet the standards of GMP would mean a significant expansion of this document and a lot of duplication of other existing documents in Volume 4. Having two sets of standards would be confusing, could raise difficulties at time of inspections and ultimately negatively affect patient safety.
  A repetition of much of Volume 4 not only leads to unnecessary duplication of work but would require repeated revisions. Indeed, experience shows that the updating of chapters and Annexes in Volume 4 are very frequent meaning that a stand-alone document for ATMPs that duplicates requirements of these chapters and Annexes would be in constant revision. This would not be required if the document was an annex to Volume 4.

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We believe the disadvantages and risks of this approach would actually exceed the benefit of having a single reference document for ATMPs.

- Sections on Scope and Principles should be added to the introduction of the proposed document to clearly define the following elements:
    - The scope of the document; for example, the consultation document often discusses broader overarching Quality Management requirements and principles and CMC issues rather than the narrower scope of GMP;
    - The aim and the legal position for the document, if this is to remain a stand-alone document;
    - Clarity on the Quality standard to be achieved; for example, this document refers to a Pharmaceutical Quality System where as ICH Q10 specifies that a suitable quality standard should be used and this could be a GMP based QMS or could, for example, be EN ISO based.

Finally, Celyad encourages the Commission to organize, before finalisation of GMP for ATMPs, a focused meeting grouping together ATMP manufacturers, the Inspectorate Working Group, the EMA and the European Commission, to discuss the above-mentioned key aspects and ensure patient safety by applying identical quality standards.

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