Bone Therapeutics

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To: Unit B5 – "Medicinal products – policy, authorisation and monitoring"
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European Commission
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Submission of Comments on the Consultation Document: Good Manufacturing Practice for Advanced Therapy Medicinal Products

Dear,

Bone Therapeutics SA is a Belgian-based bone cell therapy company specializing in addressing unmet medical needs in the field of bone fracture repair and bone fracture prevention. Bone Therapeutics develops both autologous and allogeneic innovative cell therapy products. The company falls within the EU definition of a small and medium size enterprise.

We welcome the aim of this document to provide specific guidance for developers of ATMP. The new Consultation Document has been significantly expanded compared to last year Consultation Document and we have noticed that several of our proposed changes have been incorporated, for which we are very grateful. However, one of our main recommendations was to design the document as an Annex to the EudraLex Volume 4 of the "The rules governing medicinal products in the European Union" rather than as a separate stand-alone document has not been followed. BONE THERAPEUTICS SA firmly believes this document, by reproducing some but not all of Eudralex Volume 4, fails to provide the specific and targeted guidance required by the developers of ATMPs. As a result, we reiterate our previous recommendation that the targeted guidance this document aims to provide on the GMP requirements for ATMPs is incorporated into an Annex of Volume 4, similar to what was done for the blood derived products in Annex 14 for instance. This would enable the text

to focus only on the GMP elements that need specific adaptations for ATMPs taking into account the particularities of the individual product types (TEP, GTMP), with clear cross-referencing to other requirements that are common to all medicinal products for human use. This approach would add visibility as it would only deal with the specific elements for ATMPs and it would serve its purpose to act as a clear and comprehensive reference document for all ATMP manufacturers. Subsequent revisions will also be much simplified as these would be limited to changes required due to progress in the field of ATMPs.

Bone Therapeutics SA urges the Commission to rethink releasing this as a stand-alone document for the following reasons:

1) Key components from EudraLex Volume 4 are missing, such as for instance product recall handling and notification. Since many hospitals/university based groups and SMEs developing ATMPs may be relatively inexperienced in GMP and licensing requirements, we believe this will cause confusion and may lead to disparate practices resulting in different quality standards;
2) A repetition of much of EudraLex 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 EudraLex Volume 4 are 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 were an annex to Volume 4A;
3) A perceived divergence of quality standards over time may arise from GMP expectations which could be detrimental to the field;
4) As many aspects of GMP are not specific to ATMPs, having 2 sets of reference guides for ATMP and non-ATMP products would invite potential disparities between the two and could cause some difficulties for companies and for Competent Authorities at time of inspection. A separate guidance would prove challenging for developers with diverse portfolios;
5) The stand-alone document will be less evident to developers outside the EU.

Yours sincerely,

Benoît Champluvier,

Chief Technology and Manufacturing Officer

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