23/06/2011
EMA/CHMP/BWP/782739/2010
Committee for Medicinal Products for Human Use (CHMP)

Overview of comments received on 'CHMP/CAT position statement on Creutzfeldt-Jakob disease and advanced therapy medicinal products ' (EMA/CHMP/CAT/BWP/353632/2010)

Interested parties (organisations or individuals) that commented on the draft document as released for consultation.

Stakeholder no.	Name of organisation or individual
1	B. Klug, Paul Ehrlich Institut
2	BSI

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1. General comments – overview

Stakeholder no.	General comment (if any)	Outcome (if applicable)
2	RGM/1 and BSI welcome this advice. Some of the contents and concepts are well known and understood in some sectors, particularly pharmaceuticals and medical devices. In the ATMP area, however, there are a number of organisations that do not have experience of dealing with the issues described in the paper and so it should prove to be useful to new entrants into the market.	N/A

2. Specific comments on text

Line no.	Stakeholder no.	Comment and rationale; proposed changes	Outcome
44-46	1	Comment: Somatic cell therapy medicinal products are defined as products which have been substantially manipulated to obtain a therapeutic, diagnostic or preventive effect through metabolic, pharmacological and immunological means. This manipulation includes the expansion of the autologous cell population (Directive 2001/83/EC-Annex 1). Thus the composition of cell based medicinal products from autologous donors may include components of human or animal origin either as excipient or raw materials used in the manufacturing process. Therefore we consider that also for autologous cell based medicinal products the risk of transmitting CJD or vCJD needs to be considered. Proposed change (if any): ~~Most of the cell based medicinal products currently under clinical investigation or already in use in some members states are from autologous donors, therefore, no specific considerations regarding CJD or vCJD risk are required.~~ For cell based products from ~~allogeneic donors,~~ the WHO classification and guidelines on tissue infectivity (*WHO Guidelines on Tissue Infectivity Distribution in Transmissible Spongiform Encephalopathies 2010)*[2a] should also be considered as a part of the benefit-risk assessment of the medicinal product.	The text has been reworded. A clarification has been included stating that: “no specific considerations regarding CJD or vCJD risk are required (except if additional components of human origin are used in their preparation, and for which a risk assessment for potential TSE contamination should be considered).” This Position statement aims to provide some specific guidance and recommendations on the minimization of the risk of transmission of CJD or vCJD for ATMPs. Guidance on components of human origin used as raw materials or excipients (e.g. human albumin or plasma derived products) would be covered by the CHMP position statement on plasma derived and urine derive medicinal products (EMA/CHMP/BWP/303353/2010). The risk of components of animal origin used as raw materials or excipients in the manufacture of ATMPs should be covered as for all medicinal products by the Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 rev 3).