

Your Voice In Europe: ROADMAP feedback for Evaluation of Union legislation on blood, tissues and cells

User's data:

- Domain: Public authority
- Name: David Olszowka
- Email: david.olszowka@mhra.gsi.gov.uk
- Country: United Kingdom
- Organisation: Medicines and Healthcare products Regulatory Agency
- Headquarter: select
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Related document: Evaluation of Union legislation on blood, tissues and cells

Feedback:

The UK Competent Authority for Blood and Blood Components, the MHRA, welcomes the Commission's proposed roadmap for a comprehensive assessment of the Union legislation on blood and tissues and cells - Directives 2002/98/EC and 2004/23/EC in such an open, inclusive and transparent way.

Under section C.2. of the roadmap the UK proposes that the evaluation should also seek to provide clarity in relation to:

- *The handling of borderline products e.g. Platelet Rich Fibrin (PRF), Platelet Rich Plasma (PRP) and serum eye drops;*
- *Continuity of supply in event of major disease outbreak e.g. pandemic flu;*
- *The basis for technical assessment of efficacy in more complex and innovative EU Tissue and Cells Directive (EUTCD) and EU Blood Directive (EUBD) products;*
- *Coverage of gaps in the transition of blood and tissues and cells into human medicines / Advances Therapy Medicinal Products (ATMPs) e.g. the period of cell derivation of embryonic stem cells and induced pluripotent stem cells and*
- *Risk-based deferral periods for donors at risk of blood-borne infections which are based on current evidence and regional epidemiology, for example, endoscopy and tattoos.*