Safeguarding equal access to safe and high quality blood supply in Europe

Brussels, 22 January 2019

Is blood a good? Shifting from public health directives to ECJ cases based on consumer law

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§ Law in Context

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European Union Health Law

Themes and Implications

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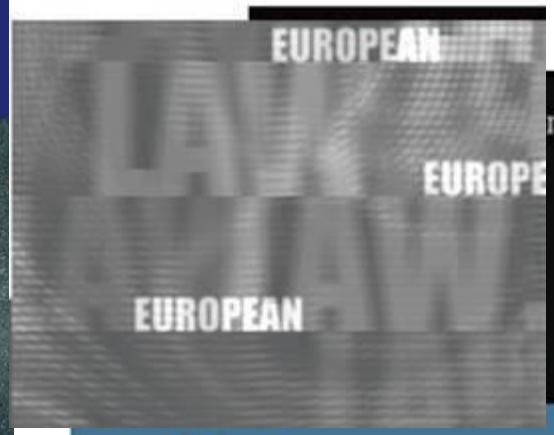

ntext

Health Law and the European Union

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The layers of EU law on blood and blood products

- Substances of human origin are not ‘products’
  - Directive 98/44/EC on the Legal Protection of Biotechnological Inventions, Articles 5 & 6
  - Directive 2002/98/EC on Blood Safety, rec 1, legal basis Article 168 TFEU
  - EU Charter of Fundamental Rights, Article 3 (2)
- Medicinal products derived from blood or plasma are ‘products’
  - Directive 2001/83/EC, Article 1, inverts *lex specialis*
  - C-512/12 *Octapharma*
  - C-421/09 *Humanplasma;* C-296/15 *Medisanus*

Making sense of EU law on blood

- Appears to be about markets, and risk regulation within markets
- But more than that
  - EU legislation articulates ethic of care
    - Blood Directive Article 20 voluntary blood donation
    - EU self-sufficiency in blood & blood products (eg Directive 2001/83, rec 19; Directive 2002/98, rec 4)
    - EU Clinical Trials Directive and Regulation prohibit financial incentives
  - EU law articulates ethic of dignity & human rights
    - Implementing Directive 2005/62/EC informed consent provisions
    - EU CFR Article 3 integrity of the person, non-commodification; Article 1 human dignity
    - See also *Neth v Parl & Council (Biotech) Brustle; International Stem Cell*
  - CJEU respects national preferences (eg *Humanplasma, Leger*), except where disproportionate protectionism (eg *Humanplasma, Medisanus*) or breach of general principles of EU law (eg *Leger*)
- However, scope for greater specificity in EU legislation, leaving less room for courts to act