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"The impact of European Union law on the regulation of advanced therapy medicinal products in France and the United Kingdom." Thesis defended by Aurelie Mahalatchimy, Under the supervision of Ms De Grove Valdeyron IRDEIC

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Thesis defended: The impact of European Union law on the regulation of advanced therapy medicinal products in France and the United Kingdom

Thesis defended successfully with honours

Abstract :

Health products based on genes, cells and tissues question the existing legal frameworks because of their advanced character, the complexity of their manufacturing processes, their human or animal origin, the therapeutic hopes they give rise to face to the unknown risks they raise, and their high lucrative potential. European Union law established the legal category of "advanced therapy medicinal products" for some of these health products to ensure the good functioning of the internal market as well as a high level of public health protection. In accordance with these objectives, the European legal regime is specific during their whole life- cycle compare to the general legal frame for common medicinal products. The implementation of this European regulation in France and the United Kingdom disrupt the sector: health safety requirements are strengthened; industrial manufacturing and market access are favoured. But the impact of such regulation is not on a par with this remarkable European regulatory anticipation: only four advanced therapy medicinal products have been presently authorised. On the one hand, a discrepancy appears between the legal sharing out of competencies coming from the treaties and the delimitation of the European and national regulations regarding the objectives of public health protection and good functioning of the internal market, but also regarding the ethical challenges raised by these medicinal products. On the other hand, the real patients' access to safe advanced therapy medicinal products still raised numerous regulatory issues

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