"Innovation & Health: New Challenges for Europe" at the 7th European Conference on Health Law, workshop by Nathalie De Grove Valdeyron, DESAPS-IRDEIC-CEEC Chair

From September 25th, 2019 to September 27th, 2019

At the Faculty of Medicine 37 Allées Jules Guesde Hotel Dieu Saint-Jacques
University Toulouse 1 Capitole

Programme

The 7th European Conference on Health Law "Innovation & Health: New Challenges for Europe" organized by the Paul Sabatier University in close collaboration with the European Association of Health Law (EAHL).

A workshop will be proposed by Nathalie de Grove Valdeyron as the Chair in European Health and Health Products Law.

Workshop conducted by Mrs Nathalie De Grove Valdeyron at the University of Toulouse 1 Capitole in September 2019

Health risk assessment and management in the European Union

The risk assessment process is essential, whether for drugs or substances whose safety must be proven before they are placed on the market. Does this process give enough attention to the particular or even unknown risks that certain medicinal products (for example, advanced therapy medicinal products, medicinal products in nanoparticulate form) may present? What are the risk assessment methodologies in this context? to which extent are they being appropriate?

Meanwhile, the European institutions are also called upon to take risk management measures. This is the case for the European Commission when it comes to placing certain products on the market (GMOs, genetically modified food products, phytosanitary products, etc.). This risk management process, distinct from risk assessment, should theoretically allow to take into account the " legitimate factors " of a socio-economic, ethical, environmental nature and in particular the precautionary principle. However, it is extremely rare for the Commission to deviate from the opinions delivered by the agencies responsible for this evaluation, thus giving an essential weight to scientific expertise. It now appears that the decision-making system using the so-called comitology procedure is dysfunctional since it leads in practice - in the absence of States taking a stance on sensitive subjects which constitute controversial scientific issues, to leave the Commission with the ultimate responsibility when it comes to placing the product on the market. This increases the feeling, in a context of mistrust towards European integration, that "it is Brussels' fault!".

This workshop will thus examine the credibility of European scientific expertise, which has been undermined by its lack of transparency and the accusations that there are conflicts of interest, in particular on the role to be played by the precautionary principle in risk assessment and management and more generally on the need to overhaul certain procedures that have shown their limits.

Traduction Monsieur Kumudithe PERERA