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Advanced Therapy Medicinal Products (ATMPs) in the light of precision (personalized) medicine

Precision medicine is expected to lead to a paradigm shift in treatment approach. Scientific and technological advances lead to another type of medicinal product: precision medicine is targeted ('personalized') medicine, as opposed to small molecule one-size-fits all blockbusters. ATMPs entail gene therapy, somatic cell therapy and tissue engineered products. This presentation explores in view of the applicable legislation about how ATMPs are regulated. The role of the committee for advanced therapies (CAT) will be explored in the marketing authorization process and what are the opportunities and pitfalls? In this presentation, the hurdles and issues to consider beforehand will be discussed i.e., How will ATMPs and precision medicine change the pharmaceutical market; what could be the legal implications; How about GMP; How about product liability; and What does the hospital exemption entail in the light of ATMPs. If the ATMP aims to treat patients with an unmet medical need, timely access opportunities may apply. Furthermore, precision medicine may need genetic data before treatment can be personalized - this concerns personal data. What issues should be considered in view of the general data protection regulation (GDPR)? In short, this presentation provides a snapshot of what should be considered in the light of ATMPs used in precision medicine. This presentation may yield a lively discussion afterwards.

Recent Publications

1. Nijland H M J, Ruslami R, Stalenhoef J E, Nelwan E J and Alisjahbana B (2006) Exposure to rifampicin is strongly reduced in patients with tuberculosis and type 2 diabetes. Clinical Infectious Disease 43(7):848–854.
2. Nijland H M J, L'homme R F A, Rongen G A P J M, Uden P Van and Crevel R Van (2008) High incidence of adverse events in healthy volunteers receiving rifampicin and adjusted doses of lopinavir/ritonavir. AIDS 22(8):931-935.

Biography

Hanneke Later-Nijland is an Attorney at law at Axon Lawyers, Amsterdam, Netherlands and moreover, she has been trained as a Pharmacist. Furthermore, she is holding a PhD in Clinical Pharmacokinetics and is a former Inspector for Clinical Trials and Pharmacovigilance at the Netherlands Inspectorate for Healthcare (IGZ). She specializes in European and national legal and regulatory issues relating to medicinal products. In her practice, she advises clients of life sciences, healthcare and litigates on a wide range of issues, often with a regulatory focus. Her areas of expertise in the medicinal products field covers marketing authorizations, reimbursement, compliance, pharmacovigilance and advertising issues. In addition, she also assists clients with product liability issues and IP and regulatory issues in transactions in the life sciences sector. Furthermore, she is a Lecturer at Leiden University Medical Centre. She regularly speaks and publishes on (new) European legislation and the impact of recent judgments in the sector.

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