Mette Due Theilade Thomsen, J Genet Syndr Gene Ther 2018, Volume:9
DOI: 10.4172/2157-7412-C3-024

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Orphan medicines and paediatric drug development

A significant proportion of orphan medicines designations are for products that receive marketing authorisation for use in children; some 60% of designated orphan medicines in Europe are intended for paediatric use. In Europe, a paediatric investigation plan (PIP) for the medicine under development will need to be agreed with the European Medicines Agency before a marketing authorisation application can be validated - unless paediatric drug development can be waived for the condition in question. Medicines authorised across the EU with the results of studies from a paediatric investigation plan included in the product information are eligible for an extension of their supplementary protection certificate. For designated orphan medicines, the incentive is an additional two years of market exclusivity. The presentation will go through the regulatory requirements for developing an orphan medicinal product intended for the paediatric population. This will be supplied with case examples.

Biography

Mette Due Theilade Thomsen is Managing Director of "PIP Adviser" which provides expert regulatory advice on EU and FDA Paediatric Investigation Plans. Mette has a career background from the authorities (Danish Medicines Agency -DMA, and European Medicines Agency - EMA) and industry. During her time in the DMA, she was in several EMA working parties and was rapporteur for various European and ICH guidelines. She later worked as Scientific Officer at the EMA with paediatric investigation plans. In Novo Nordisk, she was the overall advisor for all paediatric regulatory procedures and was a member of the EFPIA paediatrics group.

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