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REGULATORY CONSIDERATIONS FOR CLINICAL ASPECTS OF OCULAR DRUG DEVELOPMENT - ESTABLISHED AND SURROGATE END-POINTS

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The regulation of ophthalmic medications is a key public health priority, which enables patients to be confident that the ophthalmic medical treatment they receive is both safe and has a robust evidence base of clinical efficacy. Regulation of ophthalmic products across Europe, in common with all medicinal products, is overseen by the European Medicines Agency (EMA) in conjunction with the national Competent Authorities. In this United Kingdom, this is the Medicines and Healthcare products Regulatory Agency (MHRA), which plays a leading role within the European framework for protecting and improving public health and supporting innovation through scientific research and development. With an increase in the number and complexity of new ophthalmic products and new ophthalmic indications for existing biological, bio similar, cell and gene therapy agents, this represents a considerable regulatory challenge across the European regulatory network. The proposed presentation will cover the following key areas: (1) an overview of regulatory requirements and processes for clinical approval of ophthalmic drugs; (2) trends in clinical trial efficacy end-points; (3) regulatory view on use of biomarkers and surrogate end-points in marketing authorisation submissions; and (4) considerations for rare diseases conditional marketing authorisations and exceptional circumstances.

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