SERVICE SHEET

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Regulatory Affairs

Paediatric medicines development

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Paediatric medicines development

Regulation EC 1901/2006 introduced the regulatory framework in Europe relating to the development of medicines for paediatric use and the requirements to provide clinical data in the paediatric subjects.

Central to this regulation is the requirement for applicants developing new medicines to have an agreed paediatric investigation plan (PIP) in advance of submission of most types of Marketing Authorisation Application.

Preparing, submitting and gaining approval of PIPs is a significant undertaking, which has consequences for resource utilisation and timelines. The determination as to whether clinical studies in paediatric subjects are required or not has potentially large implications for the size and therefore cost of clinical development programmes. Our team has experience in advising clients on all aspects of Regulation 1901/2006 and in the preparation and submission of PIPs.

Applicability of Regulation 1901/2006

Certain legal bases for Marketing Authorisation Applications are exempt from the requirements of the paediatric regulation. Our team are able to advise you on the applicability of the peadiatric legislation as well as the other implications of selecting a particular legal basis for your application.

Paediatric Use Marketing Authorisations (PUMA)

A PUMA is a dedicated marketing authorisation for medicinal products indicated exclusively for use in the paediatric population, or subsets thereof. PUMAs benefit from certain incentives, particularly with regard to data protection. We can advise you on the potential for a PUMA and where applicable we can advise on the content of the application. Our team of quality, non-clinical, clinical and submission experts can assist with or prepare and submit (using eCTD) the Marketing Authorisation Application for you.

Preparation of Paediatric Investigation Plans

PIPs must provide a comprehensive review of the condition for which the product in question is being developed, including how the disease or condition differs between adults and children and between the various age subsets of paediatric subjects. In addition a detailed analysis of the epidemiology in paediatric subjects is required. Plans for proposed studies in children must be described and age-appropriate formulations should be considered.

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Our team has a wealth of experience in leading our clients through the Competent Authority Scientific Advice process.

PIP waivers

There are certain criteria under which a waiver from conducting clinical studies in some or all of the paediatric age subsets may be gained. We are able advise whether any of these criteria may apply to your development programme and construct the justification based on a discussion of the scientific evidence as to why a particular criterion applies to all or some paediatric sub-groups.

PIP deferrals

Under certain circumstances a deferral from conducting paediatric studies until later on in the clinical development programme may be gained, allowing a Marketing Authorisation Application in adults to be progressed. We can advise whether a deferral may be applicable and prepare the appropriate justification.

Submission of Paediatric Investigation Plans

The submission of PIPs and requests for waivers or deferrals is a multi-step process which is undertaken in accordance with strict timetables laid down by the EMA's Paediatric Committee (PDCO). We can manage this entire process, including liaisons with PDCO, on your behalf throughout, from initial notification of intent to submission, validation, distribution to all PDCO members, receipt and handling of PDCO questions and confirmation of final Commission Decisions.

Scientific advice on paediatric clinical development

The EMA offers scientific advice in relation to paediatric development which may be sought before a PIP application is made or a PIP application may be followed-up with a scientific advice request.

Our team has a wealth of experience in leading our clients through the Competent Authority scientific advice process. We can co-ordinate the process of applying for meetings, prepare questions and company justifications, prepare company briefing documents and presentations and facilitate rehearsal meetings, as well as attend meetings with or on behalf of client companies to facilitate the process and capture minutes.

Contact us:

For a more detailed discussion on how we can help you, contact us on **+44 (0)1628 530554** or email us on **info@wainwrightassociates.co.uk**

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