Expertises

Our expertise covers various therapeutic areas, and ranges from life-threatening diseases to OTC and borderline products. We have experience with all types of marketing authorisation applications and procedures (CP, DCP, MRP, national BENELUX, Referrals), and are capable to assist at all stages of the product lifecycle, starting from early phase development to the post-authorisation maintenance phase.

Regulatory strategy and health authority interactions

Eventually, successful drug development and life cycle management pass through the gatekeeping function that regulatory authorities have to protect individual and public health. PhaRA’s experts will develop with you a sound regulatory strategy to support drug development and life cycle management and will advise you on interactions with the several relevant regulatory authorities in the EU.

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EU RA consultancy during research & development

A key milestone of any early development of a candidate medicinal product is the preparation for a Clinical Trial Application for the First in Human (FIH) clinical trial and subsequent Phase-1,

Phase-2 and Phase-3 clinical trials. PhaRA's experts will assist you and will also help assuring that the EU Pediatric Regulation Requirements are met timely, that options of Orphan Drug Status are capitalized on, and that during the whole development, maximal opportunities are taken to ensure regulatory authority input is sought through Scientific Advice procedures.

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EU RA consultancy for marketing authorisation applications

Preparing and successfully filing a Marketing Authorisation Application (MAA) is a major achievement for which external staff are often required to cope with peak workloads. We offer you our expertise at an EU and national BENELUX level and extra hands to assist the team in this major exercise and guide them through the submission and approval process.

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EU RA consultancy for post-authorisation life cycle management

In order to manage a product's lifecycle in a competitive market place and environment of continuous scientific and technical progress, the marketing authorisation holders (MAHs) are faced with the need to submit Renewals, Variations, Line Extensions, Label changes, license transfers, switches of legal status, DHCP-

letters, and other regulatory maintenance responsibilities.

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Special interest areas

Therapeutic areas of special interest include infectious diseases, immune inflammatory diseases, (immuno)oncology, vaccines, and other unmet medical need areas.

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EU product information and translation

The product information (summary of product characteristics/SmPC, labelling and package information leaflet/PIL) provides the essential information for the physician, pharmacist, and patient to ensure the proper use of medicines. The PI needs prior approval by the competent authority as part of the MAA and needs to be kept up to date on an on-going basis.

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Regulatory scientific writing

Dossiers submitted to regulatory authorities include numerous scientific documents written in English. Several of our experts have developed the skill set to well present scientific data in a regulatory context. Our focus is on Module 3 regulatory co-ordinating writing as well as on co-ordinating writing of strategic documents.

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BENELUX RA consultancy services

Our BENELUX services and expertise cover submission and maintenance at national level of MAA for Rx and OTC products, notifications for borderline products, compassionate use and medical need programs, support to RMA and DHCP letters, review of advertising and promotional materials, including local RIP services in Belgium.

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Regulatory intelligence and training

At PhaRA we are passionate about knowledge acquisition and sharing. Companies contact us to train their new hires or to entertain in-house workshops on specific regulatory topics or procedures. Please get in touch if you wish to receive more

information on training modules or workshops we can offer.

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All expertises

Our expertise covers various therapeutic classes, and ranges from life-threatening diseases to OTC and borderline products. We have experience with all types of marketing authorisation applications and procedures (CP, DCP, MRP, national BENELUX, Referrals), and are capable to assist at all stages of the product lifecycle, starting from early phase development to the post-authorisation maintenance phase.

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