## 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.

## Our areas of expertise include

### Early-phase development

Early-phase development is one of the spearheads of the Federal Agency for Medicines and Health Products (FAMHP) in Belgium. PhaRA can provide regulatory advice for early-phase development projects, guide the risk assessment for First-in-Human (FIH), support the overall editing of Investigator's Brochures (IB), compile and submit clinical trial applications for FIH and early phase clinical studies in compliance with regulatory requirements (see 'Clinical trial applications'). We have experience with pre-submission meetings, National Scientific-Technical Advice (STA) requests, and Simultaneous National Scientific Advice (SNSA) to seek advice on specific trial related questions.

### Clinical trial applications

The clinical trials regulation changed the way of obtaining approval to start a clinical trial in the EU. Rather than submitting applications to national competent authorities and ethics committees of all participating member states separately, now one single application is done via the Clinical Trials Information System (CTIS) portal and 'one single decision' per member state will be provided within the timelines provided in

the regulation. The favourable climate to conduct early phase clinical trials in Belgium is retained, with a commitment by the FAMHP to issue a decision in 20 days for mono-national Phase I clinical trials.PhaRA can help companies with the preparation of the Investigational Medicinal Product Dossier (IMPD), including Quality IMPD writing, the compilation of Clinical Trial Applications (CTAs) in compliance with scientific and local regulatory requirements, the submission through CTIS and follow-up of CTAs. For trials still ongoing under the clinical trials directive a transition should be made by January 2025. PhaRA can assist companies to plan and execute the transition in a seamless way. We also have extensive experience with the strategic planning for the start-up of pivotal trials and coordination for global clinical trials.

## Regulatory strategy plan

Developing a strategic regulatory roadmap for the development and successful registration of medicinal products requires in-depth understanding of the complex EU regulatory environment. At PhaRA we can support the development of the target label and draft a sound regulatory strategy plan, optimising the use of the various incentives to drug development in the EU and the UK and possible early access tools such as accelerated review and conditional and exceptional circumstances Marketing Authorisations (MAs). We will consider the need to seek scientific advice or protocol assistance, the opportunity to obtain orphan drug designation, potential eligibility for the PRIME scheme, and compliance with the paediatric regulation. We advise you on the appropriate legal basis for your Marketing Authorisation Application (MAA) and the recommended filing route (CP, DCP, MRP, NP, UKMA (UK), UKMA (GB)). We help you to streamline regulatory milestones from the early development phase to regulatory approval and beyond.

## Liaising with regulatory authorities

On your behalf, we liaise with the European Medicines Agency (EMA), Rapporteur, Reference Member State (RMS), Concerned Member States (CMS), and national agencies. Over the past years, we have established good contacts with competent authorities in several EU countries, and at the EMA.

### Scientific Advice

Scientific advice or protocol assistance can be of great value for drug development, however, its preparation demands an intense effort from the project team. Whether advice is obtained from the EMA, at a national level or as part of the simultaneous national scientific advice, it requires profound knowledge of the procedure, careful planning, strategic thinking, and convincing writing skills to complete the process successfully. We offer our skills and knowledge to coach the client team, to help prepare high-quality briefing books, to prepare the team for meetings with the EMA/SAWP or national agencies, or to attend them on your behalf.

### Paediatric Investigation Plan (PIP)

The paediatric regulation came into force in the EU on January 26, 2007. All European marketing authorisation applications for new medicines, which are not authorised in the EU prior to the implementation date, have to include the results of studies carried out in children of different ages, unless a deferral or a waiver has been granted. The Paediatric Committee (PDCO) determines what these studies must be and describes these in Paediatric Investigation Plans (PIPs). The timely submission of a PIP and a successful PIP procedure are therefore of key importance for the filing of both adult and paediatric applications in the EU. The paediatric obligation also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that has already been authorised and patented.PhaRA has first-hand experience with the

development and submission of Waivers, initial PIPs, Modifications to agreed PIPs, Compliance checks, and PDCO interactions. Post-Brexit, PhaRA can also help companies submit their UK-PIP through the dedicated MHRA Submissions portal.

### Orphan Drug Designations (ODD)

PhaRA supports companies to understand the orphan drug legal framework in the EU and to obtain orphan drug designation for medicines for rare diseases. PhaRA has extensive experience with the preparation and submission of the Orphan Drug applications and post-designation activities, including annual reports. PhaRA can advise on orphan related opportunities, such as protocol assistance, fee reductions, market exclusivity, and potential for conditional MA.

### Vaccines

Vaccines are medicinal products that induce an immune response against the antigen(s) that is/are administered. To date, most vaccines are administered prophylactically for the prevention of infectious diseases. However, therapeutic vaccines are also being developed of which the aim is to induce an immune response in subjects that have already been infected with an infectious agent or against proteins expressed by cancer cells in patients with cancer.Vaccine antigens are complex molecules of biological nature i.e. live attenuated or inactivated viruses, inactivated bacteria or toxoids, polysaccharides extracted from bacteria or recombinant proteins produced in systems such as E. coli, yeast or human cell lines. Viral vector based vaccines  and RNA/DNA based vaccines also are under development.While from an EU and Benelux procedural perspective, there may be limited vaccine specificities, from a scientific and development RA perspective (scientific advices, paediatric investigation plans, MAA’s, post approval life-cycle management), specific expertise is warranted

which is evidenced by the fact that within the network of EU Agencies, a few have developed specific expertise in vaccine regulatory assessment and often act as rapporteur/co-rapporteur and RMS. One of these is the Belgian FAMHP, which has developed as a Centre of Excellence in vaccine assessment.PhaRA has extensive experience with different vaccine projects, both preventive and therapeutic, and can assist with all regulatory activities  from early development to life cycle management.

### Marketing Authorisation Applications and Procedures

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 , UK and Benelux level and extra hands to assist the team in this major exercise and guide them through the submission and approval process. We review submission components, help compiling the application and respond to questions. We are able to run your regulatory procedure, or support specific steps in the process. We have experience with all types of MAAs and EU procedures (Centralised, Decentralised, Mutual Recognition, or National Procedures), including preparation and participation in pre-submission meetings, oral explanations or discussion meetings. We have also been involved in re-examination procedures and Referrals.

### Post-authorisation maintenance support

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, post-authorisation measures, and other regulatory maintenance responsibilities. PhaRA can help MAHs to cope with these regulatory challenges and administrative burdens.

## Product information (PI) 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. PhaRA can support companies as of the initial development of the target label, draft/update the PI compliant with European and national requirements, handle QRD conversions, provide high-quality translations in all Benelux languages, and organise translations for the other EU languages. We can also coordinate art work and readability testing, and can be instrumental for compliance checks and proofreading.

## Regulatory intelligence and training

At PhaRA we are passionate about knowledge acquisition and sharing. Pharma companies contact us to train their new hires or to provide 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. Intelligence exercises to picture the regulatory landscape for your product or to keep up with the continuously changing legislation can also be outsourced.

## Regulatory scientific writing

Dossiers submitted to regulatory authorities include numerous scientific documents written in English. Several of our experts have 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 such as paediatric investigation plans, orphan drug dossiers, scientific advice packages and Module 2 components.

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. PhaRA is the selected provider of the Clarivate BELUX regulatory intelligence services.

Infectious disease and (immuno)oncology

Through years of concrete client project support, several of our RA experts have developed specific expertise in these areas, especially in antiviral medicinal products as well as in the unmet need area of oncology drugs.

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