

## **Procedure for submitting a portfolio meeting request to the FAMHP:**

### **What is a portfolio meeting ?**

Typically a portfolio meeting, is a high-level informative meeting with senior representatives from the FAMHP (i.e. both experts, EU representatives and heads of department) organized by the National Innovation Office which allows applicants to present their company, the different company activities (e.g. at European and (inter)national level), the drug development pipelines, the therapeutic areas in which they are actively involved or intend to explore, the latest scientific developments and challenges, regulatory challenges.. The scope of a portfolio meeting may cover all therapeutic areas in which the applicant is involved or may be limited to a specific field: eg. oncology, early phase development, vaccines in line with the domains of excellence of the FAMHP, or any other therapeutic area.

### **Why requesting a portfolio meeting ?**

More importantly, this type of informal meetings creates the unique possibility for drug developers to engage in an early dialogue with the FAMHP, to create a safe harbour for initial discussion of potential critical issues (e.g. scientific, regulatory, strategic) and to create a mutual understanding and long-lasting partnership with the FAMHP which is of key importance to facilitate new innovations and to accelerate market access of new, promising drug products. In particular in therapeutic areas where an unmet medical needs exists, portfolio meetings may be very useful and worth to consider prior to engaging in formal procedures (e.g. Scientific-Technical Advice (STA), joint STA-Health Technology Assessment (HTA) advice, Clinical Trial Application (CTA), Compassionate Use/Medical Need Programme (CU/MNP), Early Temporary Access-Early Temporary Reimbursement (ETA/ETR)). In this context, the National Innovation Office has foreseen the possibility to allow experts from the Belgian HTA authority (i.e. RIZIV-INAMI) to participate in the Portfolio Meetings with the FAMHP as observer if the applicant wants to address issues that may also be relevant from an HTA perspective in a future stage. This approach may certainly be very helpful in view of submitting a joint STA-HTA advice request to FAMHP at a later stage in time.

Portfolio meetings can also present a great added value for applicants by getting a better insight on the multiple activities and scientific committees/working parties in which the FAMHP is involved in at both (inter)national and European level and the various domains of expertise covered by the FAMHP. Subsequently, it provides applicants a better view on which potential role the agency could play in view of future submissions, provision of ad hoc expertise in function of new drug development projects & strategies, triggering scientific/regulatory discussions at (inter)national and European level through its representatives at different committees/working parties.

## **How to submit a request for a portfolio meeting ?**

Applicants can request for a portfolio meeting simply by sending a written request to the National Innovation Office by using the following e-mail address: **innovationoffice@fagg-afmps.be**

The initial request should clearly describe the scope of the Portfolio meeting and motivation. Applicants can propose target dates for the meeting with the FAMHP in their meeting request. Normally such meeting should be requested at least 2 months in advance of the proposed meeting date/period. The applicant should provide the slides and list of attendees at least 2 weeks in advance of the meeting. The FAMHP normally foresees 2,5 hours for every portfolio meeting but this can be modified upon request of the Applicant if adequately justified.

After the meeting the Applicant is requested to provide a short summary of the meeting highlights to the National Innovation Office within one month after the meeting for information purposes.