An Interview with Mr. Hugues MALONNE

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How does the FAMHP, as regulatory agency, facilitate research and development in Belgium?

As the CEO of the FAMHP, I can confirm that our agency is committed to make safe and effective innovative therapies available to patients and healthcare professionals in a timely manner. We offer an attractive environment for clinical trials by maintaining short timelines for mononational phase I trials and taking a leading role in an important part of the multinational clinical trial procedures. We aim to keep in direct contact with the stakeholders and inform them when needed. We furthermore are investing a lot of time in our European involvement, as stakeholder for initiatives to keep Europe attractive for conducting clinical trials.

Another important aspect is that before the submission of a clinical trial procedure, all sponsors can request scientific and technical/regulatory advice (STA) for medicinal products, drug-device combination products, in vitro diagnostics (IVDs), as well as blood, cells and tissues through our National Innovation Office and Scientific Technical Advice Unit. This service has been available for medical devices since 1 January 2025. In specific cases of national STA, we foresee active patient expert engagement to ensure that innovative medicinal products and healthcare products that are being developed, would address the most relevant patient needs and that the clinical research conducted, would generate maximum outcomes.

Through active participation in the European innovation network and in EU funded projects initiatives, we specifically support small and medium enterprises and academia. We offer 75% fee reductions for small and medium enterprises, academia seeking national STA for medicinal products and a full fee waiver for national STA requests in

relation to future clinical trials to be conducted in Belgium. Additionally, the FAMHP is also actively involved in the ACT EU initiative which aims to facilitate and accelerate large, multinational clinical trials across Europe via the simultaneous national scientific advice process (the former pilot has been validated as a formal process by the Heads of Medicines Agencies in January 2025) and pre-CTA advice pilot.

To ensure that the patients have continued access to medicines after clinical trials have ended, and while awaiting the marketing authorisation and commercialisation, we offer the possibility to apply for compassionate use programmes or medical need programmes for groups of patients with a chronically, seriously debilitating or life-threatening disease, who cannot be adequately treated for that indication with another authorised and reimbursed medicinal product other than the one covered by the programme.

To facilitate R&D for substances of human origin (such as blood, cells and tissues) we have a dedicated service that coordinates the exchange of information between the relevant services of the FAMHP. This service acts as a bridge to advanced therapy medicinal products (ATMPs) or stable derivatives of blood and plasma. Strategically, it is important to note that we are actively involved in the R&D Bioplatform, an initiative of the Belgian government aimed at making Belgium an even more attractive biopharmaceutical hub.

What are the main challenges for the FAMHP in its role as facilitator of R&D?

Since 2021, many challenging European regulations went into force such as the Clinical Trial Regulation (CTR), the Medical Device regulation (MDR), the In Vitro Diagnostic Regulation (IVDR) and the New Veterinary Regulation (NVR). The implementation of these required major updates of processes and procedures. Simultaneously new EU portals (Clinical Trial Information System, Eudamed) and EU databases (Union Product Database) are in development or have been released. In view of the revision of the pharmaceutical legislation the European Medicines Agency (EMA) is putting in place a Product Management System.

We provide feedback during the development of these portals and once finalised, we need to integrate the new regulations in our processes. This requires additional capacity and collaborations with external partners, such as ethics committees. A specific challenge for the CTR has been the transition of clinical trials from the old legislation to the new one. For the MDR and the IVDR, a coordinated assessment still needs to be established. Additionally, together with the other member states we aim to facilitate the submissions of combined trials (CTR-MDR and CTR-IVDR). For both procedures, pilot

procedures are ongoing: the European Combine project deals with combined trials for medical devices and medicinal products. The FAMHP has launched a national pilot for combined studies including an IVD and a medicinal product.

Other new EU Regulations and Directives (e.g. SoHo, HTA , EHDS and the horizontal legislations such as the UWWTD) and legal acts (e.g. AI, Cybersecurity, the upcoming Biotech Act) that may impact the agency's future way of working, are carefully being followed up proactively in order to prepare the FAMHP in a timely manner. Regarding the ongoing general review of the pharmaceutical legislation, we support the focus on need-driven developments to address important unmet medical needs.

As the life science sector and healthcare climate rapidly evolve, the FAMHP needs to keep its expertise up to date within several domains such as digitalisation (use of real-world data), ATMPs, complex clinical trials and drug/device combination products.

In this context the FAMHP is currently developing a new and unique IT expertise management system in collaboration with the Federal Public Service for Health, Food Chain Safety and Environment. This system will facilitate the scientific and regulatory core tasks of the FAMHP in the next ten years and expand the external expertise networks of the FAMHP.

Ensuring timely and safe access for patients to essential and innovative medicinal products, medical devices, and IVDs remains the FAMHP's core mission. This is especially important as we face three major challenges. First, medicine shortages. Second, the need to keep medical devices, including IVDs, available on the market despite a longer certification process. And third, antimicrobial resistance, which requires us to ensure antibiotics remain accessible while using them as little as possible.

During the Belgian presidency, the FAMHP organised a two-day meeting with the other European competent authorities for medical devices and IVDs. In one of the sessions, the FAMHP and KU Leuven focused on the regulatory challenges that the new European IVD Regulation brings for rare disease diagnostic tests and more specifically for hospital developed diagnostics. Additionally, the FAMHP will participate in the development of a European guidance on in vitro diagnostics for orphan/rare diseases.

How does the FAMHP position itself in a European context?

The FAMHP is a strong partner within the European Medicines Regulatory Network (EMRN) and collaborates very actively with the European Commission, the European Medicines Agency, the Heads of Medicines Agencies, the Medical Devices Coordination Group. The agency closely follows the new developments such as accelerated clinical trials in Europe, Safe CT, Big Data, shortages, antimicrobial resistance and drug

repurposing.

The FAMHP is also actively involved in several EU4Health Joint Actions, particularly the Joint Action on capacity building “IncreaseNET” that aims to optimise and enhance collaboration and interactions with other National Competent Authorities operating in the EMRN.

The FAMHP has selected fields of excellence: vaccines which is already in place and ATMPs which is being prepared. Moreover, further reflection is ongoing to develop a field of excellence regarding medical devices. This strategic focus is essential for the agency to serve patients effectively in a rapidly changing environment.