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Overview of FAMHP achievements and accomplishments in the context of the Belgian presidency

From 1 January 2024 to 30 June 2024, Belgium chaired the Council of the European Union, the body in which the 27 member states set the political direction and priorities of the European Union. During this period, the FAMHP organised over 20 events and meetings to promote cooperation and dialogue among member states and with European institutions. In addition, the FAMHP provided expertise to many important European initiatives. Time for a recap.

Conclusions of the Council of the European Union on the Future EU Health Union

The European Commission's legislature is coming to an end and the composition of a new European Commission will be proposed around October 2024. Within the Council of the European Union, member states discussed the future of the European Health Union. This led to a document of 'council conclusions', outlining agreed public health priorities. The points included in the conclusions will guide the mission statement of the next European Commissioner for Health and Food Safety.

The FAMHP has actively participated in the negotiations and identifies the following elements as key priorities.

- Measures to improve the security of supply for essential medicines, medical devices, and in vitro diagnostic medical devices.
- The call for a European Critical Medicines Act to reduce import dependency of critical medicines and raw materials to avoid shortages.
- A common, voluntary strategic approach to medicine stockpiling.
- The incorporation of a needs-based approach within EU policy priorities, starting with the creation of an independent database to identify the unmet needs of patients and society. Belgium plays a key role in this new approach through the NEED project, led by the Belgian Health Care Knowledge Centre (KCE).
- Call for stronger collaboration within regional initiatives on access to innovative medicines.
- Ambitious countermeasures to combat antimicrobial resistance, including the development of European guidelines to reduce antibiotic consumption.
- A strengthening of the EU clinical trial ecosystem, including a coordination mechanism to streamline clinical trial funding for optimal preparedness and response to public health emergencies related to infectious diseases.
- A comprehensive strategy to identify environmental risks in the pharmaceutical production chain.
- The establishment of the EU Health investment Hub.

Negotiations on the new European pharmaceutical legislation

The European Commission proposed a review of the European pharmaceutical legislation in April 2023. During the 21 negotiations of the Working Party on Pharmaceuticals and Medical Devices, significant progress was achieved, particularly in addressing medicine shortages, promoting innovation incentives, improving access to medicines, repurposing of medicines, addressing unmet medical needs, orphan medicines, and paediatric medicines. Moreover, the first reading of the chapters on procedures and authorisations was completed. On 21 June 2024, European health ministers discussed this progress. The negotiations will continue under the Hungarian presidency.

The Critical Medicines Alliance

The Critical Medicines Alliance was officially launched during the Belgian presidency. This alliance, a result of a Belgian initiative, aims to prevent and solve medicine shortages by strengthening medicine production

capacity and improving international cooperation. In practical terms, a strategic plan with a set of policy recommendations to strengthen security of supply is expected by the end of this year. Meanwhile, the Health Emergency Preparedness and Response Authority (HERA) has completed a study that identified 11 critical medicines. The FAMHP remains closely involved within the alliance: for instance, the FAMHP's CEO, Hugues Malonne, is part of the steering board until the end of 2024.

Results from the Heads of Medicines Agencies (HMA) network
As president of the Heads of Medicines Agencies, a network of directors of European medicines authorities, the FAMHP organised several high-level discussions on pharmaceutical policy. A host of concrete actions resulted from these successful meetings.

- There is a strong support for the development of a curriculum that includes training and professional development programmes for the experts of the medicines authorities, as a continuation of the ongoing IncreaseNet Joint Action under EU4Health that aims to strengthen the network's capacity.
- The Commission was asked to propose an EU Joint Action on artificial intelligence (AI), focusing on capacity building, training and good governance.
- The impact of new legislation in various policy areas on the pharmaceutical sector was highlighted. A vigilance system was proposed to assess the impact of new legislative proposals, identify problems, share knowledge, and take a joint position when necessary.
- Finally, the focus was on strengthening the supply chain. The HMA will prepare a document with a problem statement and solutions for diversification and cooperation within the network.

The Belgian presidency also hosted the first joint meeting of the HMA, NCAPR (National Competent Authorities on Pricing and Reimbursement and Public Healthcare Payers) and HTA HAG (Heads of Health Technology Assessment Agencies Group). The meeting gathered high-level representatives from the key institutional actors involved in the medicine lifecycle. It offered a unique opportunity to enhance early-stage dialogue and collaboratively discuss issues of common interest.

Conference on unmet health-related needs
On 17 and 18 April 2024, the FAMHP, the National Institute for Health and Disability Insurance (NIHDI) and the KCE organised a conference on unmet health-related needs as drivers of policy and innovation within healthcare. Today, decisions on the development and commercialisation of medical interventions often happen based on a developer's initiative, rather than being based on defined priorities that reflect the needs of patients and society.

During five panel discussions, experts stressed the importance of an independent approach to define these needs and develop strategies for research and innovation. The conference also underlined the need for a coordinated approach at both EU and member state levels and the use of scientific evidence to identify priority health needs. Next steps include establishing an adequately funded, independent research infrastructure at EU level and a mechanism driven by member states to assess and prioritise health-related needs. Next, a strategic plan developed at the EU level should effectively respond to identified urgent needs, coordinating and guiding public support and regulatory incentives.

Technical meetings organised by the FAMHP
During the presidency, the FAMHP organised over 20 technical meetings and events. Some interesting conclusions and concrete actions resulted from these, which will be discussed in a more comprehensive report after the summer. Let's give a short preview.

- Promoting the 3Rs (replacement, reduction and refinement) in animal testing in the context of pharmaceutical testing. Early this year, stakeholders worked together to develop regulatory acceptance

criteria for micro-physiological systems, such as organ-on-chip technology. The results will be used to revise the EMA guidelines for regulatory acceptance of 3R testing approaches, ultimately encouraging the adoption of these new technologies for medicine testing and reducing the number of animal testing.

- In March 2024, the medical device working groups met to discuss progress on the new regulation for in vitro diagnostic medical devices. This regulation will not only make the EUDAMED database mandatory but the reporting obligation for interruptions within the distribution chain that impact public or patient health.
- The IT directors of the national medicine agencies met with content experts to identify actions on how IT support and guidance could help the experts achieve their goals.
- The increasing diversity within the European population increases the importance of subgroups in clinical trials. A technical joint meeting of the CHMP and SAWP examined how the criteria currently described in the clinical trials directive should be adapted. For now, the guideline on subgroups will not be updated as it covers all possible scenarios, but stakeholders are encouraged to include relevant subgroups in studies. Being open to societal change will help identify which specific subgroups could benefit from new treatments.
- The technical meetings and events covered many other important topics, such as the importance of risk management and audits in medicines authorities and the development of comprehensive business continuity plans and actions around information security, measures to increase the capacity to handle files, joint communication campaigns to best inform citizens within the EU and the essential cooperation of enforcement officials in the fight against illegal medicines and the online promotion of medicinal trends, such as Ozempic and Botox.

Sharing knowledge, information and experiences remains indispensable to protect and improve the health of patients in Europe. The FAMHP remains committed to working together within these working groups and committees after the presidency.

> "The Belgian presidency of the Council of the European Union was a successful period of intensive cooperation and dialogue between the FAMHP, and our national and European partners. Belgium played a pivotal role in fostering collaboration and achieved concrete results in several areas. These results will contribute to strengthening the European Health Union and protecting the health and well-being of European citizens. I want to express my gratitude to all FAMHP staff who have contributed to this presidency, both in terms of content and organisation. A special thanks to those colleagues who have gone above and beyond to maintain our regular tasks with the same efficiency and speed."

Hugues Malonne
CEO of the FAMHP

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