Minutes – Cancer Medicines Forum

September 4, 2025, 2:00pm – 5:00pm CET; Teams Meeting

Chairperson: Caroline Voltz on behalf of Francesco Pignatti (European Medicines Agency, EMA)

Co-chairperson: Denis Lacombe (European Organisation for Research and Treatment of Cancer, EORTC)

Cancer Medicines Forum members: European Organisation for Research and Treatment of Cancer (EORTC), European Society of Medical Oncology (ESMO), European Haematology Association (EHA) and International Society of Geriatric Oncology (SIOG)

Observers: Organisation for Economic Co-operation and Development (OECD), HTA body (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, IQWiG), patient representative (Patvocates), industry representative, European Society of Paediatric Oncology (SIOPE), International Association of Mutual Benefit Societies (AIM) and European Social Insurance Platform (ESIP)

Guests: Zorginstituut Nederland, The Netherlands; European Society of Oncology Pharmacists, Hamburg, Germany

Welcome and adoption of the minutes of the previous meeting

The Chairs welcomed the members, observers and the guests. The minutes from the previous meeting were adopted without comments.

Upcoming CMF Workshop – 14 November 2025

The EMA provided an overview of the upcoming CMF workshop agenda, scheduled for 14 November 2025 at the EMA Headquarters.

The first session which is by invitation only will explore how to facilitate academia-led optimisation trials in the EU, with an emphasis on study design and conduct considerations that reflect real-world clinical practice, clarifying stakeholder roles, regulatory requirements, and promoting collaborative approaches. The aim is to have a dedicated closed meeting involving clinical trial assessors, CMF members, and academic investigators to find practical and constructive solutions, with a particular focus on oncology.

The second session will be public and identify best practices for incorporating optimisation into drug development programmes and explore potential collaborative approaches that encourage treatment optimisation research in the post-marketing setting. The aim of this session is to foster collaboration between academia and industry in the context of the CMF (final agenda available here).

During the discussion, stakeholders highlighted that the workshop marks an important milestone for the CMF, building on last year's progress in developing potential strategies to address existing gaps. Moreover, it is acknowledged as a further opportunity to advance its multi-stakeholder approach and address challenges through collaborative dialogue. Lastly, the second session is recognised as an opportunity to address how post-marketing optimisation trials may be facilitated in the EU, focusing on study design and conduct considerations that reflect real-world clinical practice.

Activities of the European Society of Oncology Pharmacists and collaboration opportunities

The European Society of Oncology Pharmacists (ESOP) provided an overview of the work developed by the society, which is composed of 4,000 members across 75 countries worldwide, outlining its current activities and areas of focus.

The organisation aims to support optimal cancer treatment globally and has five key focus areas, known as the *big five*: education and training of oncology pharmacists; recommendations for the safe handling and administration of drugs; quality management; research and development; and pharmaceutical care. ESOP's commitment to broader societal issues, such as medicine production safety and environmental sustainability, was also emphasised.

ESOP acknowledged the work of the CMF in addressing challenges faced specifically by oncology pharmacists, particularly regarding investigator-initiated trials and novel trial designs. Difficulties surrounding the definition and regulatory requirements of low-intervention clinical trials and Investigational Medicinal Products were also highlighted, noting the operational complexities in differentiating standard care from clinical trial treatments.

During the discussion, it was highlighted that drug–drug interactions could represent an important area for future consideration, as patients in real-world clinical practice frequently take multiple medications as well as herbal formulations, which are traditionally not permitted as concomitant therapies in clinical trials. Consequently, assessing interactions requires an integrated approach that considers multiple metabolic pathways and combined effects, with potentially relevant research questions to be explored in the post-authorisation setting.

Update on the study determining the optimal treatment duration of an antibody–drug conjugate in patients with previously untreated advanced urothelial cancer

The EORTC provided an update on the treatment optimisation study in bladder cancer, which aims to determine the optimal treatment duration of an antibody–drug conjugate in patients with previously untreated advanced urothelial cancer. To support discussions with potential funders, a return-on-investment analysis has been conducted using a tool designed to demonstrate the potential financial benefits of this de-escalation study.

Currently, funding discussions are ongoing with different EU healthcare systems, which have been receptive and supportive, even though they do not necessarily have a framework that systematically foresees investment in such research. The aim is to launch this study as a pilot, involving financial contributions from healthcare systems towards trial execution, with the anticipated return including access to the study results and dataset.

During the discussion, stakeholders raised the possibility of structuring the trial in a modular manner, enabling countries to focus on data and outcomes relevant to their national context. Nevertheless, the necessity for an international trial design was acknowledged, considering the large sample size required. Lastly, the possibility of securing broader European funding, such as through the European Commission, was raised as a potential enabler. However, there are currently no funding calls available that would support such a trial.

CMF 2024 workshop: report and publication update

The EORTC provided an update on the manuscript reporting on the CMF Workshop 2024. The final draft is currently under review by co-authors for final acceptance and will be submitted to the *Journal of Cancer Policy* thereafter.

Update on the new mandate for the CMF

The EMA provided an update on the draft mandate for the CMF, developed under the Healthcare Professionals Working Party (HCPWP) and the Patients and Consumers Working Party (PCWP). The draft mandate has been prepared and will be discussed at the upcoming meetings of the HCPWP and PCWP. It will then be circulated to member organisations and observers for review and feedback.

Next CMF meetings

The CMF will meet on a quarterly basis and below an overview of the remaining dates for 2025:

- 2 December at 2pm CET
- 2 March at 10am CET
- 23 June at 2pm CET
- 3 September at 2pm CET
- 8 December at 2pm CET