Minutes – Cancer Medicines Forum Teleconference

March 31, 2022, 08:30 – 12:00 CET

Chairperson: Denis Lacombe (European Organisation for Research and Treatment of Cancer (EORTC))

Co-chairperson: Francesco Pignatti (European Medicines Agency (EMA))

Scientific coordinator: Caroline Voltz-Girolt (EMA)

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

Observers: Organisation for Economic Co-operation and Development (OECD), HTA body - Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG), patient representative (Patvocates), industry representative

Objectives of the Cancer Medicines Forum (CMF)

Participants agreed that what has been lacking so far is a forum where discussion surrounding treatment optimisation can take place between the different stakeholders involved in developing anticancer treatments.

The objective of the CMF is to bring together representatives of academic organisations to explore how EMA as an agency can contribute towards addressing optimisation issues, while also identifying other opportunities for collaboration.

The CMF has a clear academia focus: it will be a forum where the members can share priorities and the issues they experience. It is also joined by observers like patient advocates, and experts from health technology assessment and the pharmaceutical industry. This will help explore the relevance of the academic discussions for other stakeholders.

The possibility to expand the CMF into a proper multi-stakeholder forum will be evaluated in the future.

The CMF is not an advisory body or a decision body from the EMA: it will develop general recommendations.

Transparency and pluralism are key: CMF will aim to publish what is discussed during meetings and to eventually propose workshops for multi-stakeholder input on specific topics and recommendations.

Discussion of two case studies

Two cases were discussed as possible examples of where optimisation is needed and possible. The cases are meant to provide examples of gaps and to start the discussion about possible recommendations form the forum.

Treatment optimisation in advanced prostate cancer

- Moving from continuous to intermittent administration of prostate cancer agents in patients responding well to treatment
- Treatment de-escalation could result in:
    - No significant reduction in overall survival
    - Significant improvement in quality of life
    - Reduction in cost by up to 50-60%
    - Increased affordability of these drugs for lower-income countries
    - Optimised reimbursement schemes in European countries

Treatment optimisation in triple-negative breast cancer

- Reducing the duration of immunotherapy treatment in patients responding well to treatment
- Treatment de-escalation could result in:
    - Young women being spared from immunotherapy-related toxicity
    - Society and EU Member States being spared from reimbursing a costly treatment

The two cases focused on de-escalation of treatment duration and schedule, but treatment optimisation also aims to define the optimal dose, target population, treatment combination, and biomarkers.

Based on the two case studies, possible key aspects of treatment optimisation studies were discussed, including associated challenges and potential solutions to address them:

- Identification and labelling of research questions
- Methodology (need for randomisation, use of real-world data, adoption of pragmatic trial designs)
- Role and contribution of different stakeholders (including academia, industry, regulators, payers, health technology assessment bodies, doctors, patients)
- Funding (public or private)
- Timing (pre-approval or post-approval)
- Recruitment of patients
- Regulatory and legal aspects
- Availability and reporting of datasets.

The forum decided to continue discussing similar cases to foster the discussion on some of these topics. Eventually, some of these could become separate topics to develop into recommendations and possible actions.

Interaction with other initiatives, communication of outputs, practical considerations

The CMF will seek interaction with other initiatives and organisations and operating in the field to:

- Explore synergies
- Avoid overlap and duplication of efforts
- Increase visibility of CMF and treatment optimisation

The CMF aims to publish the outcomes of its discussions:

- Summaries will be published on EMA Academia webpage
- Recommendations and scientific papers on specific topics of meetings

Expansion of CMF to other members will be reviewed after the pilot phase has concluded one year.

CMF meetings will be organised three to four times per year: Next meeting in June 2022