Minutes – Cancer Medicines Forum

December 20, 2022, 11:00 am – 13:00 pm CET; WebEx

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, International Association of Mutuals (AIM),

Guests: experts from the Utrecht University and Dutch Medicines Evaluation Board

Introduction and adoption of the minutes of the previous meeting

SIOG (International Society of Geriatric Oncology) representative and a representative from ESIP (European Social Security Platform) will be invited as observers for the next CMF meetings.

A representative from OCCA (Optimal Cancer Care Alliance) will be invited for the next CMF meeting for specific topics.

The dates of the next CMF meetings were agreed as well as the proposal to have a workshop in Q4 of 2023 (proposed topic will be decided at the next CMF meeting).

EORTC mentioned that pragmatic cancer trial in metastatic prostate cancer patients have been agreed with the EC as a 1st treatment optimisation study. This was a proposal made as the previous CMF meeting and is a global successful 1st case. It involved prostate patients organisation to discuss and agree on the clinical endpoints to use.

EORTC also mentioned 2 additional successful call in glioma and retroperitoneal sarcoma.

Discussion on EMA Post-authorisation safety and Efficacy studies

EMA gave a presentation on the regulatory framework of post-authorisation efficacy and safety studies and explained the differences between the conditional MA, MA under exceptional circumstances and full MA with imposition of post-authorisation studies. Some examples were mentioned where regulatory action (such as restriction of indication) were taken based on the submission of study results of post-authorisation safety and efficacy studies.

It was also mentioned that treatment optimisation aspects should ideally take place and be discussed during the development phase (such as for orphan designation when applicable, SA and Paediatric Investigation Plan).

Developing criteria to guide the choice of methodology and related quality standards:

EORTC presented a flowchart referring to how treatment optimisation should be performed:

- Conducting studies in the post-authorisation setting: which questions require which methodology?
- Discussion on the methodological characteristics and challenges of treatment optimisation studies: equipoise, randomisation, real-world data, etc.
- Developing criteria /decision tree for selecting optimal methodology as a function of the clinical situation and the question being addressed.

Further discussion will take place at the next meeting.

Discussion on feasibility of randomized clinical trials in the post-authorisation setting

A specific study conducted by Utrecht University and the Dutch Medicines Evaluation Board was presented on the feasibility of randomised studies in the post-marketing studies. An overview of the research project made on the clinical trials used in post-marketing phase was presented. One aspect that influences the feasibility is the differences in availability of a medicine between countries, possibly complicating trial conduct. Additionally, comparative studies with standard of care were deemed meaningful post-marketing and not against placebo. In some cases, there is also competition between products and trials which can delay the post-authorisation studies. The analysis of this study will be published together with specific recommendations on the feasibility of these studies.