EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Launch of EMA's Cancer Medicines Forum with Academia

1. Purpose

This paper describes the establishment of the Cancer Medicines Forum (CMF) with Academia and lays out the principles under which the CMF will operate.

2. Background

Since its inception, EMA has granted marketing authorisations to many medicines that have gone on to play an important role in the treatment and management of various types of cancers. The field of oncology has seen the emergence of major innovations in recent years, including the arrival of personalised medicines, immunotherapies and advanced therapy medicinal products. Such innovations have helped cancer patients across Europe by offering them new tools in their fight against the disease. However, at the time these anticancer medicines enter the market, many uncertainties often remain with respect to their integration into the existing array of treatments, stemming from a lack of available data on how they should be applied in clinical practice. Furthermore, there is an opportunity to develop approaches tailored to the characteristics of the patient and the disease, to maximise benefits and minimise harms to patients, and to ensure high standards in cancer care.

For example, it may be unclear how a new drug should be combined with existing treatments like surgery, radiotherapy and other pharmacological interventions in such a way that the effectiveness of the combination of treatments is maximised while the side effects are minimised. Moreover, at the time of authorisation, some uncertainties may remain regarding the optimal target population, dose and duration of treatment. For instance, investigating de-escalation questions could potentially lead to reducing the use of unnecessary treatments and reducing toxicities. Addressing these uncertainties may require the conduct of studies to collect robust data that will adequately fill existing evidence gaps. Research that focuses on optimising the way medicines are used in clinical practice has been referred to as treatment optimisation research.

Acknowledging the importance of academic research in general and treatment optimisation research in particular for the oncology field, EMA has decided to establish a forum where academic organisations and learned societies operating in the cancer space can discuss the evidence gaps that they encounter in clinical practice and explore how the European regulatory system can be leveraged to address them.

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EMA has collaborated with the EORTC under the EMA framework for collaboration with academia to establish this forum.
To this end, reports from the forum will be communicated publicly and disseminated to the regulatory network and external stakeholders. However, the views from the forum should be seen exclusively as stakeholder engagement communication and should not be understood as expert advice requested by the Agency, or as representing the views of the Agency.

3. Objective

The broader aim of the forum is to establish a platform through which oncology academic organisations can engage with the regulatory network and contribute to fostering high standards in cancer care.
The specific objective of the CMF is to explore how EMA can contribute towards addressing evidence gaps encountered with respect to the use of anticancer medicines in clinical practice and facilitate treatment optimisation research.

4. Meeting organisation

The CMF will be co-chaired by EMA and a member from Academia. The co-chairs will support the CMF administratively by selecting topics for discussion based on the input of the CMF members, by organising and moderating meetings of the CMF, and by producing meeting reports. CMF members will include representatives of key academic organisations from EMA's Healthcare Professionals Working Party operating in the field of oncology, as well as experts/observers from the regulatory network and stakeholder groups.

5. Organisational aspects

1. Planning

The first meeting of the CMF (so called 'Kick-off meeting') is taking place on the 31st of March 2022

2. Pilot phase and selection of members

The CMF will initially undergo a one-year pilot phase during which only a selected number of persons and organisations will be invited to attend its meetings on a quarterly basis. Upon conclusion of the pilot phase, the working procedures of the CMF will be re-assessed.
During the pilot phase, the meetings will be conducted as closed-door meetings with a view to conducting open meetings in the future.
There will be no duty of confidentiality with respect to the issues discussed and a report will be published after every meeting under the responsibility of the chairpersons.

3. Ground rules for EMA contributions

The CMF will operate under the following ground rules regarding EMA's contributions:

- The views expressed in the forum should be seen as a stakeholder engagement activity and should not be understood as those of the Agency or attributed to the EMA or its scientific committees;

- Similarly, any views expressed in the forum should not constitute or be understood as expert advice requested by the Agency in the context of its statutory roles such as the scientific assessment of marketing authorisation applications.

6. Communication

After every meeting of the CMF, a meeting report will be made available on the Academia web page of the EMA website.