17 February 2025
EMA/418198/2024
Oncology Working Party
Human Medicines Division

Consolidated 3-year rolling work plan for the Oncology Working Party

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Work plan period: January 2025 – December 2027 (with a first review point after one year)

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1. Strategic goals

The Oncology working party (ONCWP) has set the following main strategic goals:

1.1. *Short-term strategic goals*

- Review the need for development of new guidelines/reflection papers in oncology based on emerging needs as identified from EMA scientific advice (SA)/protocol assistance (PA), qualification procedures and from CHMP discussions.
- Revise current guidance documents to maintain up-to date information in line with ongoing needs and based on the most recent scientific insights.
- Provide the requested and state-of-the-art support to the EMA Committees in the Oncology and Haematology areas.
- Provide input to recurrent issues of interest upon request by CHMP with a view to provide guidance to assessors and maintain consistency in the evaluation of medicines.
- Plan and conduct scientific symposia in line with EMA/CHMP strategic objectives, see section 2.2
- Further expand the oncology European Specialised Expert Community (ESEC), including communication and training strategies
- Further expand the collaboration with international regulators to promote information exchange and potential convergence on key areas of interest. See also 2.3. and 2.4.
- Contribute to multistakeholder platforms and their deliverables on key areas of interest to the Agency and the network, such as the Cancer Medicines Forum (CMF) or workshops organised by the Agency, other regulators or learned societies.

1.2. *Long-term strategic goals*

- Increase oncology network capability and expertise building by developing newsletters, training materials and promoting information exchange between assessors, leveraging collaborations with academic and learned societies and building on the experience gained so far and published guidance (see also under "Short term strategic goals”).
- Foster collaborative evidence generation by delivering appropriate guidance documents, promote information exchange and contributing to multistakeholder platforms with the aim to further optimise oncology drug development, embrace innovation and contribute to a robust assessment of new cancer treatments.
- Continue to actively contribute to global initiatives with other regulators for the benefit of cancer patients.

2. Tactical goals

2.1. *Guidance activities*

(A) Activities ongoing/to be finalised in 2025

Action: Lead

Guideline on the clinical evaluation of anticancer medicinal products, EMA/CHMP/205/95 Rev.7

Target date	Concept paper for revision 7 release for public consultation in Q2 2025 To be developed in collaboration with MWP
Comments	

Guideline on the clinical evaluation of therapeutic radiopharmaceuticals in Oncology

Target date	Concept paper release for public consultation in Q4 2024 (EMA/CHMP/451705/2024) Draft Guideline release for public consultation in Q4 2025

Action: Contributor

Reflection paper on the patient experience data in clinical trials

Target date	Draft Reflection paper released for public consultation in 2025
Comments	Provide specialised oncology input along with other working parties

Reflection paper on Cardiovascular Safety in Oncology

Target date	Draft reflection paper to be released for public consultation: Q2 2025
Comments	Led by cardiovascular working party (CWP)

(B) Activities to be started in 2025

Revision (7th) of the Guideline on the clinical evaluation of anticancer medicinal products and Appendix 1, EMA/CHMP/205/95 Rev.6.

Target date	Draft updated guideline release for consultation in Q4 2025
Comments	Linked to the Concept paper on Revision 7 to be released in 2024

2.2 Training and workshop activities

- The ONCWP will engage with stakeholders in workshops on issues arising in the oncology field including workshops organised by Academia, Learned Societies, CMF and other relevant stakeholders. Areas of interest identified in 2025 include development in rare cancers such as soft tissue and bone sarcoma, elderly cancer patients, therapeutic radiopharmaceuticals, and clinical endpoints in oncology.
- Develop through the oncology ESEC community regular communications and dissemination of other key information
- Host a number of oncology ESEC webinars for the network and expand invitations to other regulators or other stakeholders such as HTA assessors where relevant to share new knowledge on emerging issues and to foster interaction between assessors.

2.3 Communication and Stakeholder activities

2.3.1. European level

- Continue to engage in the Cancer Medicine Forum and contribute to the publication of relevant outcomes
- Continue to engage with learned societies (e.g. International Myeloma Society (IMS), European Society for Medical Oncology (ESMO), European Hematology Association (EHA)) to tackle existing or emerging issues with support from the relevant Committee/working parties, e.g. in the area of rare cancers, precision medicine, and innovative communication via participation to workshops or collaboration of research project on topics relevant to the work of the Agency.
- Contribute to potential collaboration and information exchange with HTA stakeholders to promote transparency and inform bridging from Benefit/Risk to relative effectiveness assessment.
- Continue to engage with relevant stakeholders, such as Industry, healthcare professional and patient's organisations via dedicated meetings (for example with Patients' and consumer's working party or healthcare professional's Working Party) or multistakeholder workshops on different topics, e.g. post-approval commitments in rare cancer, registries, or evidence-based methods for patient involvement.
- Collaboration with ACCELERATE Paediatric Strategy Forum for Medicinal Product Development; Annual forum hosted by the EMA and Interaction with Academia and patient organisations to foster a patient-centred drug development dialogue

2.3.2. International level

- Participation to the "Oncology cluster" teleconferences and other joint meetings or workshops with international regulators where relevant. Meetings have been established with international regulators to discuss new trends in depth, e.g. new endpoints, study designs, RWD and RWE.

2.4 Multidisciplinary collaboration

Input upon request from other working parties or committees for the development of guidelines

3. Operational goals

3.1 Pre-submission activities

- Product-related support in the field of oncology upon request from relevant groups (e.g. Innovation Task Force)
- The OncWP will provide product-related support in the Oncology field upon request from Committees (e.g. COMP, CHMP) and other working parties such as the SAWP during pre-submission phase.

3.2 Evaluation and supervision activities

- Support in the field of oncology upon request from Committees and other Working Parties.

4. List of Abbreviations

CMF – Cancer Medicines Forum

COMP - Committee for Orphan Medicinal products

IMS International Myeloma Society

EHA - European Haematology Association

EORTC – European Organisation for the Research and Treatment of Cancer

ESEC - European Specialised Expert Community

ESMO - European Society for Medical Oncology

HTA – Health Technology Assessment

RWD, RWE – Real World Data, Real World Evidence

SAWP – Scientific Advice Working Party