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Human Medicines Division

Consolidated 3-year work plan for the Oncology Working Party (ONCWP)

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Vice chair:	Olli Tenhunen

Work plan period: January 2022 – December 2024 (with a first review point after one year)

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1. Strategic goals

Although, great improvement has been made in the treatment of cancer throughout the EU in recent decades, there are still many challenges to overcome. The "Europe's Beating Cancer Plan" aims to include actions across the entire disease pathway including prevention, diagnosis, treatment and survivorship (4 pillars) and to operate in interconnectivity with EU Cancer Mission that has 3 pillars: prevent what is preventable, optimise diagnostics and treatments and support quality of life.

The ONCWP is committed to contributing within its remit to EU's "Europe's Beating Cancer Plan".

Furthermore, the ONCWP will foster interaction with patients, academia, industry and payers. It will aim to develop a multi-stakeholder forum for interaction with academia focussing on treatment optimisation and explore new approaches for eliciting patient input and benefit-risk communication. The strategic goals include hosting meetings and workshops, promoting a pro-active publication strategy and providing more opportunity for training exercises for the network.

1.1. Short-term goals

- Publication of the 6th revision of the anticancer guideline
- Contribute to the single arm trials (SAT) paper (collaboration with BSWP)
- Develop Q&As in collaboration with Scientific Advice Working Party
- Plan and conduct scientific symposia
- Continue working on the EMA- European Society for Medical Oncology (ESMO) collaboration
- Establish the oncology European Specialised Expert Community (ESEC), including communication and training strategies
- Further develop the collaboration with international regulators.
- Establish a multi-stakeholder EMA Forum on Cancer Treatment Optimisation.

1.2. Long-term goals

- Establish a workshop strategy with academia and interested parties
- Further elaborate on the EMA- European Network for Health Technology Assessment (EUnetHTA) collaboration
- Explore ways of interaction with industry
- Draft training material for assessors
- Draft reflection papers on specific topics related to oncology
    - Plan 7th revision of the anticancer guideline
    - Establish a publication strategy

2. Tactical goals: activities/projects to deliver the strategic goals

2.1. Guideline activities

- Finalise Guideline on the clinical evaluation of anticancer medicinal products, EMA/CHMP/205/95 Rev.6
- Develop *Questions and Answers* documents on emerging topics from scientific advice and evaluation of marketing authorisation applications. See also 2.4.

2.2. Training activities

The ONCWP will be providing:

- Host a number of webinars/training sessions and possibly face to face workshops for the network to share new knowledge on emerging issues and to foster interaction between assessors
- Host a training session on statistical consideration for non-statisticians, e.g. estimands, KM a number curves, impact of missing data, etc.
- Develop through the oncology ESEC community regular communications in the format of newsletters and dissemination of other key information

2.3. Communication and stakeholder activities

Publications

- Prepare a proactive publication strategy on products and regulatory guidelines

Stakeholder meetings

European activities

- Organising workshops/meetings for regulators to discuss relevant current topics, e.g. histology agnostic/biomarker-driven indications, new endpoints, RWE, RWD, etc.

  Quality of life (QoL) instruments workshop with relevant stakeholder: impact of new technologies, the increased role of patients directly involved in reporting their perceptions of a treatment, new types of treatments such as targeted agents and immune therapy with mechanism-based toxicities that prompt the need to revisit the way Quality of life (QoL) instruments need to evolve in a rapidly changing field, and how they might contribute to important societal decision making in health care systems. Thus, there is a need to re-assess the role, process and interpretation of QoL instruments in the era of precision oncology
- Establish a multi-stakeholder EMA cancer forum on treatment optimisation to identify research priorities focussing on academia. The forum will complement existing stakeholder interactions and collaborations (e.g., ACCELERATE)
- EMA-ESMO collaboration: co-operation for rare cancers, precision medicine, and innovative communication. Two workshops on rare cancers and a research project on standards of evidence will be organised.
    - EMA-EUnetHTA collaboration and further engagement with regular and frequent dialogue with HTA stakeholders

- Drive adoption of novel practices in cancer drug development that facilitate clinical trial authorisation and HTA acceptance.
- Enable information exchange with HTAs to support bridging from B/R to relative effectiveness assessment.
- Maximise sharing of information under confidentiality arrangements to speed up HTA. Address the fears of cross-influencing by clearly describing the different roles/decisions. Communicate about these.
- Explore how possibilities to approximate authorisation procedures (in time, content, format) could foster convergence
- Approach difficult underlying issues such as the different basis of HTAs and EMA work/endpoints/evidence base

- EMA-Industry collaboration (e.g. EFPIA): explore new ways of interaction via dedicated meetings or regular workshops on different topics, e.g. post-approval commitments in rare cancer, registries, etc. The outcome of these workshops can be publications in scientific journals.
- EMA-Patients organisations collaboration:
  - There is growing contribution and involvement of patients in EMA activities.
  - Formal evidence-based methods for patient involvement, e.g., quantitative elicitation of patient preferences can be further explored.
  - The EPAR structured benefit-risk analysis has improved communication somewhat but still falls short from the transparency and communication that could be achieved using visualisations and innovative benefit-risk communication, e.g. elicitation of patient/expert preferences. There is an opportunity to improve and modernise the mode of communication of our regulatory decisions.
- EMA-HOVON (Dutch-Belgian Cooperative trial Group for Haematology Oncology) collaboration:
  - Develop partnership with HOVON to undertake fundamental research in strategic areas of regulatory science. Explore possibilities for future collaboration on different matters, e.g. testing different scientific hypotheses prospectively in HOVON sponsored trials, but also retrospectively on previously conducted trials by HOVON.
- Collaboration with EMA-SIOP(E)6th ACCELERATE Paediatric Strategy Forum for Medicinal Product Development of CAR T-cells in Children and Adolescents
- Build a platform for interaction with patient organisations to foster a patient-centred drug development dialogue

International activities

- Participation ONCWP at international meetings, workshops and conferences.
- Participation in International Oncology cluster monthly teleconferences and joint activities with international regulators

- Quarterly 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

- Publication on Single arm trial in conditional marketing authorisation (SAT-CMA):
  - Discuss the concept of comprehensiveness of data for CMAs
- Biomarker-driven indications:
  - Analyse the EMA experience of marketing authorisation applications for histology independent indications in oncology
- Therapeutic benefit of combination of therapies and the contribution of each mono-components:
  - Reflect on the need to update the anti-cancer guideline on the contribution of mono-components in combination therapies in oncology and comparing EU experience with other regions across the world
- Real World Evidence/Real World Data (RWE/RWD)
  - Discuss the currents strengths and limitations of RWE/RWD
  - Analyse the requirements for use of RWE/RWD to be used in regulatory decision-making in oncology.
- Co-development of medicines and companion diagnostics (CDx)
  - Analyse the relevance of mutational signatures as biomarkers, including NGS, and other omics technologies which are increasingly used in oncology
- Investigate how the benefit-risk assessment could be expanded to incorporate patient preferences.
  - Conduct a number of surveys amongst patients, in additions to SAG-O members for given procedures under evaluation

3. Operational goals: medicinal product-specific activities

The ONCWP will provide product-related support upon request from Committees and SAWP.

Priorities for 2022

4. Guidelines

4.1. EU Guidelines

Action: Lead

Guideline on the clinical evaluation of anticancer medicinal products, EMA/CHMP/205/95 Rev.6

Target date	CHMP adoption in Q2 2023
Comments	Lead: Pierre Demolis

Action: Lead

New: Appendix to the Guideline on the clinical evaluation of anticancer medicinal products, EMA/CHMP/205/95 Rev.6; wording of the therapeutic indication

Target date	CHMP adoption in Q3 2023
Comments	Ongoing

Action: Lead

New: Guideline for the development of therapeutic radiopharmaceuticals

Target date	Concept paper to be drafted in Q2 – Q3 2023 Adoption by the CHMP and Publication of the concept paper in Q3 2023
Comments	Drafting group including ESEC members, experts in nuclear medicine, methodology experts and statisticians, co-ordinated by the ONCWP

5. Training for the network and knowledge building

- The WP organised assessor trainings for the network to share new knowledge on emerging issues and to foster interaction between assessors - Q3/ Q4 2023

6. Contribution to dialogue and engagement with stakeholders and external parties

6.1. Workshops

- EMA – ESMO collaboration workshop on rare cancers. – ongoing in 2023
- EMA – ESMO research project on standards of evidence – ongoing in 2023.

6.2. Collaboration with Interested parties and other stakeholders

- Cancer Medicines Forum (CMF); this is a multi-stakeholder forum serving as a communication channel with the academic community in oncology, to address questions and issues related to oncology drug development emerging from the academic community in a multidisciplinary environment. the CMF met regularly in 2022 – regular meetings planned for the next years
- EMA – EUnetHTA collaboration with HTA stakeholders in relation to bridging from B/R to relative effectiveness assessment.
- EMA – Industry collaboration (e.g. EFPIA): explore new ways of interaction via dedicated meetings or regular workshops on different topics, e.g. post-approval commitments in rare cancer, registries, etc. The outcome of these workshops can be publications in scientific journals.

7. European collaborations

- See above section 3

- Initiatives as part of the EU Beating Cancer Plan
- Collaboration with the EORTC in emerging PRO- HRQoL scales and instruments.

8. International activities

- Participation in International Oncology cluster monthly teleconferences and joint activities with international regulators
- Quarterly meetings have been established with international regulators to discuss new trends in depth, e.g. new endpoints, study designs, RWD, RWE, etc.