



ESMO Statement for the first consultation on the WHO Europe Access to Novel Medicines Platform 8 February 2023

The European Society for Medical Oncology (ESMO) shares and endorses WHO's commitment to the promotion of Universal Health Coverage (UHC), which means that everyone, everywhere, should have access to the health services, when and wherever they need them, without risk of financial hardship. It includes the full range of essential health services, spanning health promotion to prevention, diagnosis, treatment, rehabilitation and palliative care. These issues of access and sustainability are central pillars of ESMO's public health policy.

ESMO has submitted statements on Universal Health Coverage at many United Nations (UN) and WHO meetings, for example:

- 1. The 2019 UN multi-stakeholder meeting on UHC: The ESMO statement supported UHC for cancer patients based on ESMO's commitment to health as a human right, not a privilege. The ESMO statement requested that the UN Political Declaration on UHC state that "countries must guarantee their entire population universal health coverage benefit packages that ensure financial protection for patients, and include a core set of comprehensive, safe, affordable, effective and quality cancer prevention, diagnosis, treatment, and palliative care services". This would contribute to reducing cancer deaths worldwide. It would also require that governments strengthen primary care, guarantee referral services to secondary and tertiary facilities, and maintain comprehensive cancer registries to measure progress.
- 2. The 2019 World Health Assembly: An ESMO statement reinforced the messages in point 1 above and noted how they would contribute to reducing cancer deaths worldwide, yield broad economic gains, and provide societal benefits.
- 3. The 2019 UN High-Level Meeting on UHC: An ESMO statement welcomed the meeting's Political Declaration on UHC and called on governments to prioritise high-impact investments in cancer care by accelerating implementation of the 2017 WHO 'Cancer Resolution' (WHA 70.12). ESMO also requested that countries pay for comprehensive essential cancer services within national UHC packages, which is currently lacking in many countries. ESMO raised awareness with WHO Member States of its tools and resources that can support countries in achieving the 3 dimensions of UHC:
 - The <u>ESMO-ASCO Global Curriculum in Medical Oncology</u> supports training the necessary workforce to 'increase population coverage'.
 - The evidence-based <u>ESMO Clinical Practice Guidelines and ESMO Pan-Asian Adapted Guidelines</u> can guide decisions to cost-effectively 'expand essential health services'.
 - The <u>ESMO-Magnitude of Clinical Benefit Scale (ESMO-MCBS)</u> can help prioritise cancer medicines to frame appropriate use of limited public and personal resources to 'reduce the financial burden of health services'.

ESMO shares the conviction that "urgent collective action is required to ensure equitable access for all patients in need, and to safeguard the sustainability of health-care systems and the innovation process."

To date ESMO has invested substantial resources in producing the evidence-based ESMO Clinical Practice and Pan-Asian Adapted Guidelines, as well as Expert Consensus Statements that set the standard of cancer care.

In addition, ESMO has collected data and mapped the discrepancies in access to and availability of anti-cancer agents in Europe and in the rest of the world. The <u>ESMO surveys</u> have been cited by WHO as the most comprehensive assessment on the availability of cancer medicines globally in the <u>2018 WHO Technical Report on</u> the pricing of cancer medicines and its impacts.





Furthermore, in order to promote value in cancer care and knowledge in the development of national formularies, ESMO has developed a robustly validated approach to the evaluation and grading of the magnitude of clinical benefit of new cancer therapies. The ESMO-MCBS highlights those treatments that provide substantial benefit to patients and helps distinguish them from treatments with less substantial or lower patient benefits.

Since 2016, where relevant, the ESMO-MCBS scores are incorporated in the <u>ESMO Clinical Practice Guidelines and the Pan-Asian Adapted Guidelines</u>, helping to provide patients with the best care options and setting the highest standards for cancer care.

Since 2019, the WHO Expert Committee on Selection and Use of Medicines acknowledges the role of the ESMO-MCBS as a screening tool to identify cancer treatments that have potential therapeutic value that warrants full evaluation for the Essential Medicines List (EML) listing. Potential new EML cancer medicines, in general, should have a score on the ESMO-MCBS of A or B in the curative setting and of 4 or 5 in the non-curative setting.

During the 2021 Oslo Medicines Initiative (OMI) consultation with non-State actors, ESMO provided suggestions and highlighted ESMO resources that can support WHO Member States in addressing issues that affect access to effective, novel, high-priced medicines and health products. ESMO's suggestions included the following:

- Harmonise the standard of cancer care, including implementation of guidelines such as the <u>ESMO Clinical</u> Practice Guidelines
- Prioritise cancer medicines with the highest magnitude of clinical benefit, which can be supported by tools like the ESMO-MCBS
- Determine the appropriate use of biosimilars. ESMO's position is published in the <u>ESMO Position Paper on</u> Biosimilars
- Harmonise the Health Technology Assessment process at the EU level, including the use of cancer medicines as a pilot for joint clinical assessments
- Address issues related to the availability of cancer medicines to patients. ESMO's data collection on the topic has been published in the <u>ESMO Availability of Antineoplastic Medicines Studies</u>
- Promote multistakeholder collaboration to implement the OMI

While we are encouraged by the statement that "national health authorities and the pharmaceutical industry agree that equitable access to safe, effective and novel medicines should be improved and barriers to access reduced, while incorporating country-specific requirements for product registration and packaging language", we are concerned by the continued objection of the European Federation of Pharmaceutical Industries and Associations (EFPIA) to price transparency which was one of the key recommendations of the OMI and which is one of the key aims of this endeavour to create an 'Access to Novel Medicines Platform'.

As an organisation without inherent conflict of interests, and with a boundless commitment to the promotion of quality sustainable care, ESMO is well placed to help bridge the gap between the interest of governments and industry in the pursuit of an effective collaborative approach to fair pricing based on the principles of solidarity, transparency and sustainability.

We hope that together we can contribute to formulating an approach to a price structure that reflects the magnitude of patient benefits (value), ensures 'reasonable' profitability, and which ensures 'adequate' incentives for research and development, while also being sensitive to the needs of countries with lesser financial resources.

In conclusion ESMO fully endorses the four main strategic aims of WHO Europe's Access to Novel Medicines Platform:

- to establish a formal collaboration mechanism to promote dialogue and knowledge exchange between Member States, non-State actors, partners and other stakeholders to identify actions to improve access to effective high-cost novel medicines;
- 2. to agree actions to improve the transparency of the markets to build trust, promote collaboration, enable horizon scanning, facilitate accountability and enable corrective actions to be implemented;





- 3. to support voluntary collaborations that focus on solidarity to achieve patient access including horizon scanning, demand aggregation and life cycle management;
- 4. to develop methodology, indicators and systems that recognize the need for sustainability of health-care systems and industry, and enable risk sharing and good governance of the market.

To facilitate this process, we propose that we build on some of the constructive suggestions proposed by other actors in this crucial sector:

- 5. A conceptual framework for Equity Based Tiered Pricing (EBTP), to ensure that ability to pay across countries is considered in the prices of innovative medicines, anchored in a principle of solidarity between countries, to reduce unavailability of new medicines and access delays.
- 6. Novel payment and pricing models, when used appropriately and tailored to the situation, can accelerate patient access to medicines, allowing payers to manage clinical uncertainties, budget impact and sustainability of the healthcare system, whilst providing sufficient incentives for innovation.

ESMO looks forward to being an active participant in the development of this important project.