Mr Olivér Várhelyi
Commissioner for
Health and Animal
Welfare
European Commission
Rue de la Loi 200
1049 Brussels

Subject: A Healthier Europe: an evidence-based approach to optimise Europe's Beating Cancer Plan

Lugano, 13th January 2025

Dear Commissioner Várhelyi,

We are writing to you on behalf of the European Society for Medical Oncology (ESMO) – a professional society representing more than 40,000 members from 179 countries and territories – to congratulate you on your appointment as Commissioner for Health and Animal Welfare and to share our thoughts on how we can support you and your team in the optimization of Europe's Beating Cancer Plan (BCP).

As you so accurately stated in your written answers[1] to the European Parliament (EP), 'combatting cancer continues to be one of the greatest challenges of our time'. Given that Europe's cancer burden is expected to grow from over 4.4 million new cancer cases in 2022 to 5.33 million in 2040[2], we were delighted to also note your commitment to 'drive forward the implementation of the BCP' and recognition that, nevertheless, 'work must continue, together with you, with Member States and stakeholders on implementing the plan and its very ambitious actions.'

The delivery of such an ambitious, and cross-cutting – not least in the research sphere, set of goals will require both an integrated approach to policy making and delivery, and the involvement of genuine experts like our members at all stages of these interconnected processes.

For example, your worthy efforts to conclude the reform of the EU pharmaceutical legislation, propose a Critical Medicines Act to address the severe shortages of medicines, lead the work on a new European Biotech Act to boost innovation in health technology assessment and clinical trials, and complete the European Health Data Space (EHDS) have the combined potential to deliver a European research ecosystem that ensures that patients with cancer across Europe have access to innovative new cancer treatments.

Most significantly though, will be your efforts 'to ensure that the (in vitro diagnostic device) regulatory framework does not have an unintended effect by stifling innovation and combines with the aforementioned legislative initiatives 'to boost the EU's competitiveness and to turn our world-leading science into marketable products, to bring academic institutions and businesses together and provide the connections to compete globally.'

Given that our members pre-empted the Draghi Report's description of the 'existential challenge[3]' facing Europe in their assessment of the impact of the unintended consequences of the implementation of the EU's In Vitro Diagnostic Medical Devices Regulation (IVDR) on oncological research, we particularly welcome your commitment to 'intensify the ongoing work of evaluating the current legislation' and would reiterate our availability to support your work in this vital area.

[1] https://elections.europa.eu/european-commission/en/varhelyi/
[2] International Agency for Research on Cancer (IARC). Cancer Tomorrow
[3] The future of European competitiveness: Report by Mario Draghi

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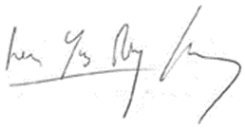
Further details about how we can support you in the full and expeditious implementation of the BCP are appended to this letter.

We look forward to hearing from you and, given both the complexity and scope of the matters at hand, would be delighted to elucidate our views in person or by continued correspondence.

Yours sincerely,



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Annex I

1. CONTINUOUS CARE IN TIMES OF CRISES

Since pandemics, conflicts or climate change induced disasters do not respect borders, it is self-evident that solutions to such crises must also be transnational. As a non-state actor in official relations with the World Health Organization (WHO), and with a presence in 179 countries worldwide, ESMO has both the international reach and grass-roots expertise to help develop and implement crisis planning to secure the delivery of care for patients with cancer. Since disruption to cancer treatment can impact significantly upon survival rates and the quality of life of patients with cancer, the EU must act to ensure that provisions for sustainable cancer care services are integrated into global preparedness planning and responses to both pandemics and emergencies. This should include securing adequate, continued, and timely access to cancer and palliative care services and medicines, the continuance of existing clinical trials, avoiding competition over scarce resources, and supporting workforce wellbeing during these periods of heightened stress.

2. IN THE VANGUARD OF GLOBAL ONCOLOGY RESEARCH

With ESMO's three established scientific journals being cited over 69,000 times and serving over 10 million articles online in 2022, our members have the requisite networks and expertise to help you secure Europe's position as a global leader in research and development. For Europe to retain its position as a key driver of oncology research and enable the development of innovative cancer medicines, cancer must be prioritised within the 10th EU Framework Programme (FP10), with specific workstreams focussing on the multidimensional causes of rare cancers, personalised cancer therapies and artificial intelligence support for clinical decision-making. Moreover, beyond providing a ring-fenced budget of at least €200 billion for FP10, the implementation of existing legislation and pending initiatives - such as the IVDR and the EHDS - within the EU's research ecosystem must facilitate rather than stymie these goals.

3. A WORKFORCE FIT FOR PURPOSE

With members ranging from medical students, to practicing medical oncologists and cancer nurses through to the CEOs of national cancer centres across all 27 Member States, ESMO has a unique perspective on the challenges facing the oncology workforce and the practical knowledge to help policymakers make informed decisions. Whilst responsibility for the funding of national health services remains with the Member States, the EU institutions can play a significant role in helping to secure an oncology workforce that is truly fit for purpose and able to deliver BCP's justifiably ambitious goals. Escalating challenges related to staff shortages, oncologists' wellbeing and work-life balance - which intensified during the COVID-19 pandemic - are impacting oncologists' ability to deliver the highest possible standards of care. As such, we welcome calls for a dedicated Directive on work-related psychosocial risks as one important measure to tackle this multifaceted challenge. In addition, we also call on the EU to increase the available funding for related professional development training programmes and to consider modernising the Professional Qualifications Directive to reflect emerging workforce challenges.

4. FOR PATIENTS, WITH PATIENTS

With oncologists collectively seeing over 4 million new patients with cancer annually, and a dedicated Patient Advocates Working Group (PAWG) adding expertise to the development of policy recommendations, ESMO has an exceptional body of global evidence upon which to draw when working to ensure that the patient voice is properly

reflected within EU policy and legislation. As Europe's circa 12 million cancer survivors can testify, the patient experience unfortunately does not end with remission. Whilst these figures are cause for optimism and testimony to our members' sterling efforts across Europe, we believe that a renewed focus on survivorship is needed to help, as far as possible, survivors regain the important aspects of their lives before cancer, and to find new pathways to a

satisfactory life going forward. With this in mind, we welcome the recent adoption of the Consumer Credits Directive, and its 'Right to be Forgotten' provision, which stipulates that health data should not be utilised when determining creditworthiness. Whilst this is a positive first step, all Member States must urgently introduce legislation that obliges financial providers to disregard cancer survivors' medical history when assessing their claims or applications beyond a prespecified and scientifically justifiable timepoint from the end of active treatment. Likewise, we are proud to be a stakeholder in the development of the non-binding code of conduct (CoC) on the fair access of cancer survivors to financial services in the EU but believe that, in due course, this must become both mandatory and extended to other critical aspects of a survivor's life, such as employment security.

5. THE TREATMENT PATIENTS REQUIRE, WHEN AND WHERE THEY NEED IT

As oncologists are intrinsically involved at each stage of the patient disease pathway, as well as in the approval processes of the attendant cancer treatments, they are well placed to advise you on both the operational and regulatory challenges hindering the delivery of optimal care to patients with cancer in Europe. ESMO's tools and resources - most notably the ESMO-Magnitude of Clinical Benefit Scale (ESMO-MCBS) - are designed to help facilitate improved decision-making regarding the value of anti-cancer therapies and can be used as supportive tools for the joint clinical assessments under the Health Technology Assessment (HTA) Regulation to improve the accessibility of cancer treatments. ESMO wholeheartedly supports the EU's efforts to reform its pharmaceuticals legislation and improve the affordability, accessibility and availability of medicines. Within the review, we believe that the development of a criterion-based definition of unmet medical need (UMN) and the scientific guidelines on the category of orphan medicinal products addressing high unmet medical need (HUMN), should be prioritised to assist the treatment of Europe's 5.1 million patients with rare cancers - an annual incidence of less than 6 per 100,000 - or ultra rare cancers. Downstream of the review of the pharmaceuticals legislation, and ahead of the entry into application of the HTA Regulation in January 2025, we call on policymakers to use all provisions within the legislation to ensure that medical oncologists' expertise can be utilised to help secure patient access to innovative cost-effective treatments.

6. PREVENT WHERE POSSIBLE, TREAT WHEN NECESSARY

As a partner of the International Agency for Cancer Research's (IARC) World Cancer Report Updates Learning Platform on cancer prevention, we are all too aware of the impending tsunami of new cancer cases - increasing from over 4.4 million in 2020 to 5.32 million in 2040 - driven by a combination of ageing populations and the rapidly evolving behavioural and environmental factors that Europe will face. The EU must react swiftly to these societal changes by revising the Tobacco Products Directive to reflect the emerging risks from e-cigarettes, legislate to reduce the risk of melanoma from ultraviolet radiation (UVR) caused by the use of sunbeds, with a special focus on the adolescent and young adult (AYA) population, and inform consumers about dietary patterns and cancer risks through, for example, the labelling of alcoholic beverages and unhealthy food products. In light of the cancer risks linked to the Human Papillomaviruses (HPV) and Hepatitis B virus (HBV) infections and given the estimated 34,000 cases of cervical cancer diagnosed annually in the EU/EEA, the EU must act to tackle vaccination hesitancy and eliminate the obstacles that limit vaccination coverage. Having recently taken welcome steps to decrease the incidence of cancer caused by occupational exposure to asbestos and environmental (air) pollution, the EU must also legislate to reduce the risk from other occupational carcinogens and environmental pollutants such as endocrine disruptors and benzene.