



Ewa Piasecka
Health Attaché
Permanent Representation of the Republic of Poland to the European Union
Rue Stevin 139
1000 Brussels, Belgium

Subject: The Polish Presidency of the Council of the EU and Europe's Beating Cancer Plan

Lugano, 18th December 2024

Dear Ms. Piasecka,

We are writing to you on behalf of the European Society for Medical Oncology (ESMO) - a professional organisation for medical oncology, representing more than 40,000 members from 177 countries and territories - to congratulate you on Poland's upcoming assumption of the Presidency of the Council of the EU and to share our views on how it can help deliver the goals of Europe's Beating Cancer Plan (BCP).

With Europe's cancer burden expected to grow from over 4.4 million new cancer cases in 2022 to 5.48 million in 2045¹, and as the estimated number of cancer deaths in Poland is foreseen to increase to over 151,000 in 2040², we believe that Poland's Presidency - which will coincide with the start of the new EU legislature - provides a unique opportunity to make significant progress towards addressing Europe's growing cancer burden.

ESMO has developed an [Election Manifesto](#) (attached) whose recommendations will be crucial for the successful delivery of the BCP. Accordingly, we would like to highlight several legislative opportunities that your Presidency could helpfully prioritise over the next semester, enclosed for your information in the Annex I below.

We thank you for considering our views and would be delighted to elucidate further, in person, or by continued correspondence.

Yours sincerely,

Prof. Andrés Cervantes
ESMO President

Prof. Jean-Yves Blay
ESMO Director of Public Policy

¹ International Agency for Research on Cancer (IARC). [Cancer Tomorrow](#).

² European Cancer Information System (ECIS). [Long term estimates of cancer incidence and mortality, for all countries](#).

Annex I

Health Workforce: We welcome [calls](#) for a dedicated Directive on work-related psychosocial risks as one important measure to tackle the ongoing healthcare workforce crisis. The tireless efforts of oncology professionals are critical in providing vital care to patients with cancer. However, the escalating challenges related to staff shortages, [oncologists' wellbeing and work-life balance crescendoed during the COVID-19 pandemic](#) with its effects still being felt today. Our recommendations to tackle the situation include an increased focus on, and investment in, workforce retention measures, the reinforcement, of a major magnitude, of training and career development programmes for young oncologists - given that efforts to replace retiring doctors are [suboptimal across the EU](#) - and the development of dedicated strategies and resources to help secure manageable workloads within congenial working environments.

10th EU Framework Programme (FP10): With the preparations for FP10 soon to commence, we are supportive of the recommendation by the [Heitor Report](#) to allocate a ring-fenced budget of at least €220 billion for the new Framework Programme given that such financial envelope is a requisite for developing the cancer treatments that citizens in Poland and Europe need. We also consider it important that the health-related workstreams of FP10 focus on multidimensional causes of rare cancers, personalised cancer therapies, and artificial intelligence support for clinical decision-making, amongst other key priorities. Moreover, the implementation of existing legislation and pending initiatives - such as the In Vitro Diagnostic Medical Devices Regulation and the European Health Data Space - within the EU's research ecosystem must facilitate rather than stymie these goals.

In Vitro Diagnostic Medical Devices Regulation (IVDR): Whilst we welcome the IVDR intent to ensure patient safety and provide a more transparent framework for IVDs, our members are increasingly concerned about how its implementation has been hindered by a lack of infrastructure, guidance, and coordination, triggering a series of unintended consequences that actually impede clinical trial development and block access to new cancer treatments. Indeed, with an estimated 238 to 420 trials to be delayed in the coming years³, we would go as far as to say that oncological research in Europe faces an existential threat as a direct result of these inadvertent ramifications. Efforts, like the [COMBINE project](#), from the European Commission, to resolve these issues are welcome and may tackle some of the challenges but are unlikely to deal fully with the fundamental challenges caused by the current legislative framework.

Recognising that the Commission is already working – through a targeted evaluation of the legislation and the COMBINE project – to resolve the challenges posed to cancer research by the Regulations on clinical trials of medicinal products, medical devices and in vitro diagnostics, we ask you to urge the Commission to commit to the continued support of these initiatives and, if they do not swiftly resolve these challenges, expedite the introduction of legislative measures to remove this existential threat posed to oncological research.

Critical Medicines Act (CMA): Noting that the BCP⁴ is explicit about the importance of ensuring access to critical cancer medicines to the delivery of its objectives - reducing the burden of cancer and ensuring equitable access to

³ New European legislation designed to protect patients is delaying clinical trials for thousands of people with cancer and rare diseases (www.efpia.eu)

⁴ European Commission (2021). [Europe's Beating Cancer Plan](#).

life-saving cancer treatments for all European patients - and that the Union List of Critical Medicines⁵ identifies essential oncology drugs that must be available to all patients across the EU, the proposed Critical Medicines Act has the potential to contribute to the delivery of the BCP's objectives by addressing supply chain vulnerabilities as well as affordability and availability challenges.

Given the axiomatic importance to the delivery of the BCP of ensuring patient access to critical cancer medicines, we urge you to take all necessary steps to ensure that medical oncologists, whose clinical expertise and real-world experience will be vital in its successful delivery, play a central role in both the development and implementation of the Critical Medicines Act.

EU's tobacco legislation: Tobacco consumption remains a leading cause of preventable illness and premature death, contributing towards many forms of cancer, and cardiovascular and respiratory diseases. This consequently accounts for nearly [700,000 deaths in the EU](#) bringing a vast financial burden on national healthcare systems. With a reference to the ESMO letter, sent on 21 November 2024, asking for your support in securing the adoption of the Council Recommendations on Smoke-and Aerosol-Free Environments, ESMO is very pleased with the recent adoption of these Recommendations, with their wider scope covering electronic cigarettes (e-cigarettes) and heated tobacco products (HTPs) and extending the coverage of smoke-free environment policies to key outdoor areas, as a positive step towards fighting tobacco pandemic. With [evidence](#) emerging that [new products](#) like e-cigarettes and HTPs pose serious health risks, and of the 'rapid increase' of vaping amongst adults who had previously [never smoked](#), ESMO believes that the EU must react to these societal changes by expediting its delayed revision of the EU's tobacco legislation, including the Tobacco Products Directive (TPD), Tobacco Taxation Directive (TTD) and the Tobacco Advertising Directive (TAD). Consequently, ESMO invites the upcoming EU Polish Presidency to prioritise tobacco control measures and put pressure on the European Commission to table a timely revision of the EU's tobacco policy to achieve the Tobacco Free Generation by 2040, where less than 5% of the population uses tobacco, as set in the [Europe's Beating Cancer Plan \(EBCP\)](#).

⁵ European Medicines Agency (2023). [First version of the Union list of critical medicines agreed to help avoid potential shortages in the EU](#).