



## The future of oncology policy

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### ABSTRACT

To ensure the previous progress seen in cancer survival rates continues as we move through the 21st century it is important to determine future effective policy related to oncology healthcare delivery and funding. Recent successes with, for example, the COVID vaccine response, the decision-making agility exhibited by governments and healthcare systems and the effective use of telehealth and real-world evidence highlight the progress that can be made with pooled efforts and innovative thinking. This shared approach is the basis for the European Beating Cancer Plan which outlines action points for governments and health systems for the period 2021–2025. It focuses on a whole government approach, centred on patients, maximising the potential of new technologies and insights across policy areas including employment, education, transport and taxation, enabling the tackling of cancer drivers in schools, workplaces, research labs, towns and cities and rural communities. Despite the plan there are still concerns that oncology policy has not adequately responded to the pace of innovation and the unique challenges generated by innovative oncological technologies. There needs to be focus on: gaining consensus on the most appropriate methods to assess and price combination therapies and cell and gene therapies, developing effective outcome-based payment models for personalised medicine and developing consensus on the ideal approach for multiple indication pricing. Finally, future policy needs to ensure pharmaceutical companies and other research organisations are adequately rewarded for innovation to ensure continued R&D and the development of innovative oncological products.

### 1. Introduction

There have been unprecedented oncology-related successes over recent years - cancer survival has doubled since the 1970s and, in the last five years, a total of 64 oncology new active substances have been launched globally [1]. Despite this, in 2020 2.7 million people in the European Union were diagnosed with cancer and 1.3 million lost their lives to it. By 2035 the number of lives lost to cancer per year is set to increase by almost a quarter [2] with a predicted economic impact of €100 billion per year in Europe alone.

The need for cooperation between countries and the optimisation of oncology policy has never been stronger. Whilst the COVID pandemic had an obvious negative impact on cancer diagnoses and patients, affecting each stage of the disease pathway from clinical research through to prevention, diagnosis and treatment, the vaccine response highlights the unprecedented progress made possible when efforts and resources are pooled. Similarly, the use of telehealth, real world data

and the newfound culture of decision-making agility have been significant factors in recent successes. However, there remains significant variation between countries. For example, despite Poland reporting one of the lowest levels of cancer incidence in Europe, the five-year survival rates are significantly lower than in other European countries [3], which may reflect challenges in the use of data that impede effective decision-making [4]. Maximising the potential of new active substances, including innovation in the areas of personalised medicine, cell and gene therapies and combination therapies, will require 'buy-in' from a number of stakeholders across the oncology landscape to ensure the removal and reduction of as many obstacles as possible. Lessons could be learned from recent experiences and used to develop effective oncology policy for the 2020s and beyond.

### 2. Europe's beating cancer plan

In February 2021 the European Commission released their vision for

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Europe's Beating Cancer Plan to be enacted 2021–2025 [2]. It looks to maximise the use of new technologies, research and innovation to set out an EU-wide approach to the cancer pathway, incorporating important aspects of prevention, treatment and care. Focusing on action points valuable to patients, survivors and their families that are supported by activities spanning multiple policy areas including employment and taxation, it aims to enhance the opportunity for adding value, eliminate inequalities in access to knowledge, prevention, diagnosis and care, allowing expertise and resources to be shared across the EU. The plan incorporates ten flagship initiatives and multiple policy objectives, set within four key areas (see below). Progress at the time of writing (early 2022) is centred on the launch of various calls and initiatives. For example, the Knowledge Centre on Cancer, the Innovative Health Partnership and the Breast Cancer Quality Assurance Scheme. Similarly the 'Regulation on Health Technology Assessment', Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA) action plan and the Strategy on the Rights of Persons with Disabilities 2021–2030 were adopted [5]. The coming year (2022) is due to see the adoption of a number of additional proposals, the establishment of EU taskforces, development and piloting of apps, adoption of maximum limits for carcinogens in foods and initial access to one million genomes, among others.

### 2.1. Prevention

As around 40 % of cancer cases in the EU are preventable, the plan aims to raise awareness of and address key factors related to preventable cancers - smoking, alcohol, obesity and the genetic predispositions at play. Action points include improving health literacy related to cancer risks and determinants; reducing tobacco smoking to less than 5 % of the population by 2040; reducing harmful alcohol use by at least 10 % by 2025; improving access to healthy diets and physical activity by setting a maximum limit for carcinogenic contaminants within food, exploring tax incentives to increase consumption of healthy food and provide investment to healthy canteens; reduce environmental pollution by interacting closely with Green Deal and Zero Pollution Action Plan; reducing exposure to hazardous substances and radiation by improving the safety of products for both consumers and professional users; and enhancing access to the HepB (hepatitis B) vaccine. The flagship initiative within prevention centres on the increased use of HPV (human papillomaviruses) vaccination with the aim of vaccinating at least 90 % of girls across the region by 2030 whilst also significantly increasing the vaccination of boys.

### 2.2. Early detection

Up to 25 Member States (MS) have introduced population-based screening programmes for breast cancer (22 for cervical and 20 for colorectal) in National Cancer Control Plans but there are coverage inequalities. One of the key flagship initiatives of the Plan is the development of a new EU-supported Cancer Screening Scheme to ensure that MS offer screening for breast, cervical and colorectal cancer to at least 90 % of their qualifying population by 2025. The Commission proposed to, by 2022, update Council Recommendations on cancer screening to ensure they reflect the most up-to-date scientific evidence, assessing advances in personalised medicine (PM), artificial intelligence (AI) and big data to, for example, extend targeted screening beyond the current three to consider prostate, lung and gastric cancer. Novel guidelines and quality assurance schemes for colorectal and cervical screening will be developed, alongside the continuous update of existing breast cancer guidelines. The European Cancer Information System, which monitors the burden of cancer, will expand to monitor and assess cancer screening programmes. Early detection (and diagnosis, see below) allows the initiation of effective and aggressive first line treatment to optimise outcomes [6].

### 2.3. Diagnosis and treatment

Cancer survival rates vary by as much as 20 % across MS so key initiatives in the plan centre around ensuring patients have easy access to affordable, preventive and curative healthcare of good quality. The plan proposes a network linking a recognised National Comprehensive Cancer Centre in every MS, and the 'Cancer Diagnostic and Treatment for All' initiative which will enhance patient access to high quality diagnostics, care and the latest innovative treatments. The latter uses Next Generation Sequencing to allow the genetic profiles of tumour cells to be shared between centres enhancing access to PM. The Partnership on Personalised Medicine, Roadmap to Personalised Prevention and the Genomic for Public Health Project will identify priorities for research specific to PM, support projects on cancer prevention, make recommendations for the roll out of PM approaches in daily medical practice and help MS develop guidelines and recommendations around the identification of genetic predisposition. The European Initiative to Understand Cancer (UNCAN) (launched under the Mission on Cancer) will help identify individuals at high risk from common cancers. Reference Networks will look at specific challenging cancer conditions which could benefit from cross-border collaboration and EU expertise. A Pharmaceutical Strategy for Europe, reform of basic pharmaceutical legislation (to propose ways to enhance access to generics and biosimilars) and a specific EU platform to support the repurposing of existing medicines will work towards enhancing access to cancer medicines.

On the regulatory side, the adoption of the proposal for a Regulation on Health Technology Assessment (HTA) by both the Council and the EU parliament could provide a permanent framework for EU cooperation on HTA providing MS with high quality HTA reports, ensuring fast access to innovative products for patients. An Inter-Speciality Training Programme, focusing on oncology, surgery and radiology will help MS address gaps in skills and equip the health workforce. AI and digital platforms in the form of the European Open Science Cloud and other High-Performance Computing programmes will rapidly test new drug combinations and assist those working on personalised treatments whilst enhancing interdisciplinary research and collaboration.

### 2.4. Quality of life of cancer patients and survivors

The Plan shifts focus from the length of time those with cancer live after diagnosis to both how long and how well people live. The primary focus is the Better Life for Cancer Patients Initiative which includes a Cancer Survivor Smart Card (to summarise clinical history, facilitate and monitor follow up care) and a virtual European Cancer Patient Digital Centre to support a standardised approach to the voluntary exchange of patient's data and monitoring of survivors' health conditions. Further work focuses on ensuring MS make full use of the Directive on Work-Life Balance for Parents and Carers, incorporating measures to facilitate social integration and reintegration to the workplace as parts of the patient journey and developing a code of conduct to ensure that cancer survivors are not unfairly penalised in the area of financial services.

## 3. Additional policy requirements and recommendations

Since the 1970s cancer death rates among those under the age of 65 have fallen by around half – the result of reductions in tobacco use, increases in early diagnosis and treatment, advances in radiotherapy and imaging, improved surgical techniques and the use of more effective anticancer drugs [7]. Following successes seen with the COVID response - vaccine response, decision-making agility exhibited by governments and healthcare systems and effective use of telehealth and real-world evidence - questions remain over whether oncology policy in Europe (and beyond) has adequately responded to the pace of innovation and the unique challenges generated by these technologies. As such, there are a number of additional policy points related to pricing and

regulation that need to be considered in order to maximise future impact.

### 3.1. Financing Innovative Therapies

Current cost-per-QALY (quality adjusted life year) methods used in several settings may not be suitable for innovative oncology medicines. Incremental improvements in methodology (e.g. adjustment for factors such as insurance value), sliding cost-effectiveness thresholds, or implementation of value-assessment frameworks have all been proposed as options to improve resource allocation decisions in the context of oncology care. Further research is needed to explore how these methodological advancements can be operationalised. The Italian Medicines Agency (Agenzia Italiana del Farmaco AIFA) have introduced a new innovativeness approach (where innovativeness allows access to dedicated funds and immediate access to regional markets) based on unmet therapeutic need, added therapeutic value and the quality of evidence [8]. There is limited evidence on the role played by the three criteria on the final decision and the impact of other variables on the innovativeness status whilst in the future there is the potential need to include a more structured-framework related to patient-reported outcome measures, the role of which is still under debate [8].

Perhaps the most valuable point is the requirement for continued encouragement of innovation. Some believe that innovative cancer drugs are excessively expensive compared to R&D costs. In reality, overall spending on cancer research and treatment can be considered relatively modest in macro-economic terms, even with high unit prices for some individual treatments [7]. Regulatory bodies and governments need to ensure that they do not unfairly or insufficiently reward innovation – pharmaceutical companies need sufficient incentives for the discovery of novel therapeutics if we are to continue seeing gains in cancer survival rates.

#### 3.1.1. Combination therapies

Recent scientific advances have increased the concurrent administration of multiple therapeutic products with distinct but complimentary mechanisms of action. Combination therapies, particularly those involving multiple in-patent therapies from different manufacturers, can present significant challenges from an HTA and financing perspective [9]. Allowing companies to work together, by updating relevant competition law, will enable innovative drug combinations to reach market. Many combination therapies improve clinical outcomes and survival, yet the sum of individual component prices often exceeds willingness to pay thresholds relative to single therapy approaches and there is little consensus on the most appropriate method of assessing and pricing combination therapies. This in turn leads to inconsistent availability of combination therapies [10].

#### 3.1.2. Outcomes-based payments in personalised medicine

PM provides tailor-made treatments based on a patient's specific genetic or phenotypic characteristics, offering tremendous potential for oncology. By nature, traditional RCT may not be possible for PM given high genetic variability and overall low patient numbers across cancer subgroups. Head-to-head trials are limited for PM leading to high levels of uncertainty in clinical evidence at the time of HTA and funding decisions [11]. The use of managed-entry agreements and risk-sharing agreements has increased over the past decade to mitigate uncertainty around the budget impact, cost-effectiveness and clinical effectiveness of technologies [12]. Outcome-based payment models in particular may help address clinical uncertainty of PM. Successful use of performance-based agreements requires established legal frameworks and strong data-infrastructure to track therapy use and outcome.

#### 3.1.3. Cell and gene therapies

These are highly specialised technologies that use genetic material to treat disease. Preliminary evidence on the use of CAR-T therapies in

leukaemia is extremely promising, offering potentially transformative benefits after a single use [13]. With high up-front costs and limited evidence on their long-term effectiveness, traditional methods of HTA with uniform discount rates may not be appropriate [14]. Further, while the budget impact of financing cell and gene therapies is low across small patient populations with relapsed/refractory disease, there is a large range of potential applications across other types of cancer [15]. As the number of cell and gene therapies increases, policy makers will need to ensure their assessment and pricing policies are fit-for-purpose to facilitate timely access to these technologies [14,16].

#### 3.1.4. Multiple indication pricing

Oncology therapies are increasingly developed for use across different cancer types. There is a need to develop novel pricing models to ensure sustainable access to oncology care, incentivise R&D and promote competition. Most settings adopt a single-price-per-molecule approach, de-linking the overall price from the value individual therapeutic indications provide. Indication-based pricing (IBP), whereby separate prices are provided for each therapeutic indication, may be a more optimal approach to maximising social welfare [17]. This approach promotes value-based pricing (VBP), and may provide the right incentives for innovation yet feasibility is limited by the practical difficulties of tracking and paying for products at indication level [18]. There is the potential for greater administrative costs in the purchasing and payment process as well as the monitoring and registering of the specific use per indication [19]. Instead, many countries have opted for weighted pricing, whereby the price of a therapy is renegotiated upon introduction of a new therapeutic use [20]. A unique single price for all indications is easier to manage than IBP but it moves away from VBP and could result in strategic company behaviour resulting in access delays [19]. Currently, no consensus exists on the best method of determining the weighted price.

## 4. Conclusions

The future of oncological treatment is exciting, with much progress to be made. To maximise the impact there needs to be effective policy that can ensure the previous gains made in survival continue. Effective policy, in Europe and beyond, is required at every stage of the patient cancer pathway, ensuring people have access to: sufficient knowledge and opportunity to make lifestyle choices limiting their risk of preventive cancers, screening for as many types of cancer as possible, quick and effective diagnosis services, fairly priced innovative treatment in a timely manner in line with patients in other countries and the tools to 'live well' as a cancer survivor. Finally, and perhaps most importantly, healthcare policy in general and pricing policy specifically needs to be designed in a way that ensures pharmaceutical companies and other research organisations are adequately rewarded for innovation to ensure continued R&D and the development of novel, pioneering oncological products.

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## Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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