The Cancer Leagues present
EUROPE'S BEATING CANCER PLAN
Towards providing better cancer control, improved cancer care and tackling inequalities throughout the EU
AIMS & SCOPE

This paper sets the framework of cancer leagues’ understanding of cancer policy and what is required to reverse the increase in cancer rates and close the inequality gap throughout the EU. The cancer leagues have a crucial role in the move towards more coordinated and harmonised cancer control efforts due to their national and regional influence and their being the main source of information and service for the general public.

Cancer is a complex set of diseases and every stage in the cancer control continuum requires different tools and services. Europe’s Beating Cancer Plan should complement and amplify the impact of national and regional cancer control plans. This paper is the result of an extensive consultation process with the ECL’s members and focuses on key areas where Europe should work as one to improve cancer control and care. It is not intended as a comprehensive blueprint for national cancer policy.

Co-funded by the Health Programme of the European Union.
ECL has received funding under an operating grant (SGA: 881569) from the Third Health Programme (2014-2020).

The information and views set out in this guide are those of the authors and do not reflect the official opinion of the European Commission, the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) or any other institution of the European Union. Neither the European Commission nor CHAFEA may be held responsible for the use which may be made of the information contained therein.
INTRODUCTION

The burden of cancer in the EU is high and rising. Cancer causes 1 in 4 deaths and is the second leading cause of death, ill health and disability in many EU countries [1], with the annual number of new cancer cases projected to increase from 3.9 million in 2018 to 4.7 million by 2040 [2].

Cancer carries with it a huge societal and personal burden due to premature deaths, loss of productivity and the costs associated with treatment and care. Indeed, the economic cost of cancer exceeds €100 billion per year [3].

The purpose and goal of Europe’s Beating Cancer Plan should be to organise society and our economy in such a way as to benefit EU citizens, cancer patients and survivors. To achieve this goal, we need a patient-centred and rights-based approach with justice, sustainability, equality, solidarity and collaboration at its centre. The following principles should be at the heart of developing the Cancer Plan:

- **Participatory Decision-Making** - Patient empowerment and patient-centredness must always be top priorities across the cancer control and care continuum.

- **Social Justice & Rights-Based Approach** - The reduction of inequality in risk factor exposure, patient outcomes and in access to screening, early diagnosis and timely and appropriate treatment and care across populations as well as between and within EU Member States should be prioritised. Similarly, vulnerable and marginalised populations (e.g. children, women, low-income households and migrants) should be given special attention.

- **Sustainable Investment** - Planning for systems change and determining how it can be applied to the fight against cancer in order to maximise the impact of interventions in the long-term is crucial. Funding should be allocated to address unmet needs and close the cancer care inequality gap. The approach to funding research should follow the same trends, as outlined in the ECL’s position paper on the EU Cancer Mission [4].

- **Health-in-All-Policies** - Cancer is a societal issue that cannot be resolved by the health sector alone. Only a truly holistic, all-hands-on-deck approach aligning, amongst others, the European Green Deal, the Farm to Fork Strategy, the Digital Economy and Industrial Strategy efforts with Europe’s Beating Cancer Plan can ensure success.

- **Cross-sector Collaboration** - There is a substantial amount of data and expertise across the continent and we must collaborate to make the most of the knowledge and tools already available and ensure effective dissemination and implementation of best practices across Europe. Bringing together different stakeholders, sectors, industries and players beyond the cancer community will be instrumental in fighting cancer.
I. PREVENTION & EARLY DETECTION

The case for prioritising cancer prevention is strong. More than 40% of all cancer cases are preventable and tackling modifiable risk factors also provide additional benefits for other non-communicable diseases (NCDs) [5]. Particular attention should be paid to applying the recommendations of the European Code Against Cancer (ECAC) in European and national policy [6].

i. Reduce use of tobacco and other nicotine products

Tobacco use remains the single most preventable cause of death and disease. In the European Region, 27% of cancer deaths were attributable to tobacco use in 2018. The WHO report, 'European tobacco use – trends report 2019', notes that almost 9 in 10 deaths (including premature deaths) from tracheal, bronchial and lung cancer in Europe are related to tobacco [7].

To address this situation, the EU Institutions and national governments have taken various tobacco control measures in the form of legislation, recommendations, and information campaigns. The Tobacco Products Directive (2014/40/EU) aims to improve the functioning of the internal market for tobacco and related products, while ensuring a high level of health protection for European citizens. The Council Directive 2011/64/EU on the structure and rates of excise duty applied to manufactured tobacco introduced high taxes on tobacco products, which are effective in reducing tobacco use, notably among young people.

Both the Tobacco Products Directive and the Tobacco Products Tax Directive require an urgent review with the aim of adopting new measures, such as:

1. Raising minimum excise duties for all tobacco products which should result in significant tax increases and smaller tax differences between cigarettes and hand rolled tobacco;
2. Enforcing mandatory plain/standardised packaging with 80% front and back pictorial health warnings for all tobacco products and/or electronic cigarettes;
3. Banning flavouring agents in tobacco products and restricting or banning flavouring in novel nicotine products, which improve the palatability and attractiveness of such products to non-smokers, adolescents and young adults;
4. Investigating a ban on plastic cigarette filters and allowing Member States to introduce such bans on health and environmental grounds.

In addition, the EU and all Member States should ensure full implementation of the WHO Framework Convention on Tobacco Control (FCTC) and its protocols.
Promote healthy lifestyles

There is substantial evidence that an individual’s cancer risk can be reduced by adopting a healthy diet and increased physical activity. Excess body fatness is thought to increase the risk of developing cancer in 12 different sites [8]. If current trends continue, obesity is expected to overtake smoking as the main modifiable risk factor for cancer. The evidence gathered to develop the 4th edition of the ECAC indicated that people who follow a healthy lifestyle have an estimated 18% lower risk of cancer compared with people whose lifestyles do not meet the Code’s recommendations [9].

Encouraging people to adopt healthier behaviours concerning diet and physical activity in their daily lives is not enough. Much of people’s behaviour is influenced by the social and economic context of the environment in which they live and work. Consequently, actions to improve diet, nutrition and physical activity must include population-wide measures addressing the social, economic and commercial determinants of health.

Considering that the European Commission will also be bringing forward proposals for the European Green Deal and the Farm to Fork Strategy, Europe’s Beating Cancer Plan should align with these initiatives to:

1. Help consumers to make informed choices about food products by implementing ‘best in class’ food labelling standards (e.g. Nutri-score);
2. Implement EU-wide nutrient profiles for nutrition and health claims following WHO recommendations;
3. Promote the adoption of a planetary health diet through implementing fiscal measures to make fresh local foods (especially pulses, grains, and legumes) more affordable and accessible, especially for people with low incomes;
4. Work with Member States to use pricing policies and marketing controls to influence demand, access and affordability of foods and drinks high in saturated fats, trans-fats, salt, and sugar;
5. Support Member States in restricting the advertising of ultra-processed food products and sugary/sweetened beverages, including on social media.

iii. Tackle Europe’s alcohol problem

Alcohol consumption is a public health problem in Europe, contributing to a vast number of chronic conditions and injuries. Ethanol and acetaldehyde contained in alcohol are classified as Group 1 carcinogens by the International Agency for Research on Cancer (IARC) and are known to increase the risk of developing at least 7 types of cancer [10]. In Europe, an estimated 10% of all cancer cases in men and 3% of all cancer cases in women are attributable to alcohol consumption [11]. However, according to a study conducted in the United Kingdom, only 1 in 10 people know the established links between alcohol consumption and increased cancer risk [12].
To tackle the impact of alcohol-related harm on cancer and other public health concerns, Europe’s Beating Cancer Plan should:

1. Better inform consumers by improving the labelling of alcoholic beverages to include prominent warning labels and nutritional information;
2. Support Member States by facilitating the adoption of comprehensive national alcohol control legislation, such as the Republic of Ireland’s Alcohol Bill;
3. Prohibit advertising on sports grounds for events where the majority of competitors or participants are children;
4. Prohibit alcohol sponsorship of sport;
5. Protect children and young people by restricting advertising and exposure to marketing of alcohol in the digital environment, especially on social media and video-sharing platforms as well as near schools.

### iv. Decrease Europe’s skin cancer burden

Radiation from the sun contains invisible ultraviolet (UV) radiation. UV radiation causes damage to the skin that, in the long term, can lead to skin cancers. Skin cancer is the most frequent cancer worldwide in predominately fair-skinned populations, and its occurrence has dramatically increased over the past few decades. The European Code Against Cancer has a clear and definitive message against the use of artificial tanning devices, commonly known as sunbeds. Sunbeds are machines designed to emit ultraviolet (UV) radiation. This UV radiation has the same damaging effects on your skin as natural sunlight and, as it is an unnecessary exposure, it should be avoided at all times.

Europe’s Beating Cancer should take steps to tackle skin cancer by:

1. Treating the regulation of artificial tanning devices (sunbeds) as a public health concern by transferring responsibility for sunbed regulation from DG GROW to DG SANTE;
2. Investigating potential collaboration with Member States in order to phase out the use of sunbeds for cosmetic purposes, and implement other public health interventions suggested by the WHO [13];
3. Implementing mandatory pictorial warning labels on sunbed devices, stating ‘sunbeds cause cancer: even infrequent usage will increase your risk of skin cancer’;
4. Prohibiting references to any supposed health benefits associated with using artificial tanning devices;
5. Increasing market surveillance of sunbeds with strict enforcement protocols in compliance with age requirements on sunbed use and radiation limits;
6. Enhancing UV protection measures in EU-level occupational health and safety regulations, paying special attention to risks faced by outdoor workers.
v. Protect citizens from harmful exposure to carcinogens in the environment

Frequent exposure to chemicals at work and during daily activities also pose health risks. The ECL call upon the European Commission to develop tangible and effective guidance and legislation to reduce citizens’ exposure to carcinogenic substances by:

1. Protecting citizens at the workplace by ensuring that employers recognise occupational carcinogens, and comply with the established exposure limit values;
2. Taking action on radon (as the second leading cause of lung cancer) by ensuring Member States publish updated national radon action plans to reduce the indoor exposure to radon, and enhance guidelines on radon mitigation for new constructions;
3. Implementing an EU-level asbestos plan, obliging Member States to support safe cleaning and removal of asbestos;
4. Taking appropriate measures to improve air quality in European urban spaces reflecting the latest WHO guidelines;
5. Ensuring the Common Agricultural Policy (CAP) strives to reduce intake of pesticide residues and revise food contact materials legislation to ensure carcinogens and endocrine-disrupting chemicals (EDCs) associated with increased cancer risk are eliminated;
6. Ensuring Europe’s Beating Cancer plan is closely linked to a comprehensive EU Chemical Strategy for Sustainability and other chemical policy frameworks to rationalise and simplify the EU’s chemical and pesticide regulations for substances causing cancer as well as the swift preparation of the long-overdue non-toxic environment strategy, and action to detoxify the circular economy.

vi. Enable population-wide access to vaccines

Few people associate infections with cancer, but nearly one-fifth of all cancers in the world are caused by infectious agents, including viruses and bacteria. Among the most important infections associated with cancers are: human papillomavirus (HPV), which cause most cervical and anal cancers as well as a fraction of oral cancers, and the hepatitis B (HBV) and hepatitis C (HCV) viruses that can cause liver cancer. Vaccines are the most effective way of preventing some of these infections. Highly effective vaccines against HBV have been available for several decades and most countries include HBV vaccination in their childhood immunization programmes. Vaccination is also highly effective in preventing infection with the HPV types that cause the majority of cervical cancers.
Europe’s Beating Cancer Plan should propose measures to:

1. Become a leader in responding to the WHO’s Global Call for Cervical Cancer Elimination as a Public Health Problem, by supporting Member States in reaching the WHO’s HPV vaccination coverage targets for girls;
2. Investigate harmonisation of HPV and HBV vaccinations within Member States’ national vaccination programmes as well as ensuring equitable access;
3. Support further research into the most effective vaccination regimens against viruses associated with cancer;
4. Collaborate with the WHO and global stakeholders to proactively address potential vaccine hesitancy and confidence issues that may arise from the introduction of generic HPV vaccines produced in emerging economies;
5. Provide clear guidance to countries on the cost-effectiveness of gender-neutral HPV vaccination strategies, considering potential global impact on vaccine supply.

vii. Build early cancer detection capacity

Detecting cancer early can effectively reduce mortality. Even in countries with well-functioning health systems and services, many cancer cases are diagnosed at a late stage where curative treatments are no longer an option. Addressing delays in cancer diagnosis is, therefore, critical for effective cancer control.

Two main strategies exist in early detection: organised screening of people without symptoms and early diagnosis of those at a symptomatic stage. In the European Union, cancer screening is recommended for breast, cervical, and colorectal cancers, as a part of organised programmes with adequate resources. European guidelines have been long-established to provide guiding principles and detailed protocols, standards and recommendations to ensure high quality services.

Europe’s Beating Cancer Plan should build on the strong track record of support for organised cancer screening programmes and prioritise building capacity for early diagnosis by:

1. Scaling up high-quality organised cervical cancer screening in those European countries with a high cervical cancer burden, in order to reach the 2030 WHO goals regarding the elimination of cervical cancer as a public health problem;
2. Updating the European Guidelines on quality assurance in cervical cancer screening;
3. Refreshing the technical annex of the 2003 European Council Recommendation on Cancer Screening taking account of developments in recent years;
4. Creating a permanent structure to continuously monitor and collect data from cancer screening programmes, which would be responsible for periodic implementation reports on cancer screening in the EU and ensure that the next implementation report on cancer screening is published before 2024;

5. Collaborating with Member States to prioritise the reduction of inequalities related to cancer screening and early diagnosis services, including overcoming financial barriers that restrict access;

6. Supporting the establishment of a permanent platform to support networks of national/regional cancer screening coordinators and leading experts in breast, cervical and colorectal cancer screening in exchanging experience, knowledge and best practices.

7. Establishing a parallel structure targeted towards early diagnosis to support Member States in pursuing effective practice and discouraging investment in practices not recommended by the WHO;

8. Developing an action plan for Member States in response to the WHO Guide to Cancer Early Diagnosis addressing health literacy, supporting implementation research, and fostering collaboration amongst Member States and neighbouring countries.

II. HEALTH DATA & CARE INFRASTRUCTURE

i. Harness the potential of health data to drive improvement in cancer control and care

Ongoing improvements in the understanding of cancer and the effectiveness, efficiency, safety and quality of preventive, diagnostic and therapeutic procedures accelerate significantly through research. Comprehensive and unbiased population-level analyses are essential for providing sound evidence about risk factors for disease, public health and the effectiveness of healthcare systems. Therefore, research efforts are affected by the possibility of sharing high-quality individual health data across the EU, the European Economic Area (EEA) and as part of global collaboration.

The General Data Protection Regulation (GDPR) acknowledged the need to address current and future health challenges by collecting and sharing health data in an ethical manner. However, many challenges remain regarding European and international research collaboration due to heterogeneous interpretation of GDPR across Member States.

In addition, further structural investments are necessary to ensure the interoperability of national cancer registries by working towards standardisation and comparability of data sources.
Europe’s Beating Cancer Plan should recognise the urgency to secure a well-functioning European Health Data Space by:

1. Supporting full coverage of harmonised population-based clinical and screening registries in EU Member States, including rare cancers, further enabling linkage with other data sources (e.g. digital health records, medical prescriptions, Clinical Patient Management System (CPMS) and biorepositories);
2. Supporting national cancer registries in expanding their capacity for the collection of data (including epidemiology, lifestyle, quality-of-life or socio-economic information) to better identify the causes of inequalities in cancer incidence, prevalence and survival;
3. Working together with Member States, the European Data Protection Board (EDPB) and supervisory authorities to harmonise the understanding of the application of GDPR regarding roles and relations when sharing data for research purposes within and outside the EU (including the EEA and the UK);
4. Investigating the best means to securely share high quality aggregate health data for scientific research and quality control, and promoting research into new anonymisation technologies (e.g. homomorphic encryption and synthetic data) to fulfil the needs for high quality research in a cross-border setting.

ii. Facilitate the implementation of Cross-border Healthcare Directives and the growth of European Reference Networks (ERNs)

The 2011 Cross-border Healthcare Directive seeks to ensure EU patients’ rights to access safe and high-quality healthcare, including across national borders within the EU as well as to facilitate closer cooperation between Member States on eHealth, treatment quality and safety, HTA and the treatment of rare diseases. However, a recent report by the European Court of Auditors has shown that the Directive’s benefits for patients are limited.

National Contact Points (NCPs) are responsible for providing information for cross-border patients. However, EU patients still face challenges in accessing healthcare abroad and only a minority of patients are aware of their rights to seek cross-border healthcare. It is important to note that, while fostering cross-border care for cases which require special treatment (e.g. rare conditions) or for patients living close to national boarders is crucial, patients should first and foremost be aware about treatment options available in their home countries, as they generally prefer to be treated close to their homes in their native language.

Established in 2017, ERNs allow healthcare providers to work across borders to tackle rare and complex conditions by pooling knowledge where there are small patient populations and a scarcity of expertise. Increasingly, ERNs provide for cross-border consultations for patients, using expertise across the ERN community.
As rare cancers account for 24% of all cancer cases across Europe, any cancer control strategy must also include specific action on rare cancers [14]. Therefore, Europe’s Beating Cancer Plan should:

1. Ensure that NCPs have the capacity and capability to effectively communicate the relationship between the Cross-border Healthcare Directive and the Social Security Coordination Regulation pathways so that patients receive clear information about their rights, options and insurance coverage as well as opportunities for patient access to clinical trials in other countries;
2. Ensure trained and proactive NCPs have been established in each EU Member State and that they follow the advice of competent ERNs to facilitate the transfer of rare cancer patients to other EU countries;
3. Build capacity in Member States, particularly in the Central and Eastern Europe (CEE) region, to ensure investment in specialised centres of excellence for different cancer types and to ensure that each Member State has at least one full or affiliated member of an ERN for rare and paediatric cancers;
4. Secure sustainable funding for ERNs specialised in rare and paediatric cancers;
5. Expand focus on adolescents and young adult patient groups, considering their distinctive medical characteristics and specific demands in terms of physical and psycho-social support;
6. Evaluate current functioning of the ERNs and consider their expansion beyond the EEA region.

iii. Streamline digitalisation and workforce optimisation

Modernisation and optimisation of healthcare services often focuses on adding additional layers in existing systems (e.g. the use of artificial intelligence and digitalisation), while still dealing with a number of pending primary challenges, such as staff shortages, workforce migration and skill gaps. With the growing importance of healthcare data and the upcoming EU plans for a European Health Data Space, it is necessary to ensure the parallel growth of health professionals’ practical skills, critical thinking and ‘innovation readiness’.

Redistribution of tasks among multidisciplinary teams of health workers for reasons of health system accessibility, effectiveness and efficiency (e.g. by enhancing the role of nurses taking over tasks previously exclusively assigned to physicians) should go hand in hand with system modernisation. If this is implemented in the correct way, it could represent a partial solution to some recurring challenges (e.g. shortages) while also developing a workforce with larger skill sets, enhanced flexibility and ability to address future challenges.
If we are to reduce inequalities in access to and quality of care in the EU, moving towards interoperability and European initiatives (e.g. the European Health Data Space, the Digital Services Act, the White Paper on Artificial Intelligence and Data) and improving European standards in education and training, will be key. Europe’s Beating Cancer Plan should focus on:

1. Building and maintaining capacity across Europe in supporting further education and skills development of hospital personnel to ensure competence, work optimisation, and overcome staff shortages. Particular attention should be paid to underappreciated professions such as oncology nurses, radiotherapy staff and palliative care specialists;
2. Expanding the role of general practitioners and other primary care professionals acting in the community in order to bring care closer to the patient and decrease its cost;
3. Ensuring access to electronic health records for all healthcare providers treating the patient;
4. Supporting clinical research to evaluate feasibility, efficacy and cost-effectiveness of non-treatment related interventions, such as self-management and e-health programmes.

### III. CANCER TREATMENTS

#### i. Foster European collaboration in clinical research

Clinical trials are the gold standard for testing a treatment’s efficacy and safety. Not only do they help drive progress in cancer research, but they also afford vital opportunities for patients who may have few other treatment options available. Europe is a global leader in clinical research, with around 5,000 cancer trials currently ongoing [15].

The 2014 Clinical Trial Regulation (CTR), due to come into force in the coming years, will be a significant improvement on the current Clinical Trials Directive, harmonising the regulatory environment for clinical trials across the EU, to the benefit of both patients and researchers. It will allow for a more efficient setup of cross-border clinical trials, and provide new technological infrastructure, including a portal and database which will simplify trial application and approval procedures. The Regulation aims to significantly reduce assessment and approval times for proposed trials. However, the implementation of CTR has been considerably delayed. Given the noted deficiencies of the current Directive, implementation as soon as practically possible must remain a priority.
Alongside the planned European Research Area and Horizon Europe's Cancer Mission, Europe's Beating Cancer Plan should benefit clinical research and trial opportunities across the Union, by:

1. Ensuring full implementation of the Clinical Trials Regulation as soon as possible;
2. Sustaining collaboration on clinical research with the UK after Brexit, as it is currently involved in 28% of all EU trials and leads on more paediatric and rare disease trials than any EU Member State;
3. Encouraging close collaboration between public authorities, foundations, academia, patients and healthcare professionals to identify and financially support areas of unmet medical need and low financial interest;
4. Making research results and data sets from all clinical trials submitted to the EMA for marketing authorisation publicly available, in order to build trust in the EU's regulatory framework and foster further research concerning a product's efficacy and safety;
5. Compelling public and private research entities to abide by the WHO Joint statement on public disclosure of results from clinical trials as timely disclosure increases value and efficiency in the use of funds and reduces reporting bias, which ultimately leads to better decision-making in health [16].

ii. Ensure a robust regulatory environment for the approval of medicines

The European Medicines Agency (EMA) evaluates the efficacy and safety of medicines. However, as data from clinical trials used for EMA assessments are often based on surrogate measures and the evaluation rarely reflects how the treatment will perform under real-life conditions, clinical trial data are often insufficient to demonstrate clear benefits for patients. Moreover, collection of real-world data post approval is often neglected.

Cancer treatments are the single largest group of new active substances receiving a positive opinion from the EMA under accelerated approval programmes, including the PRIME scheme, conditional marketing authorisation and adaptive pathways, which are primarily intended to accelerate access in areas of high unmet medical need [17]. It is not clear whether early access schemes are used as intended, and whether they result in patients being exposed to new medicines where the benefits are uncertain and safety issues unknown.
Europe’s Beating Cancer Plan should support the EMA to:

1. Ensure high quality benefit-risk assessment of patient-relevant endpoints before granting market access to medicines, stressing the need for surrogate endpoints in clinical trials to be accompanied by hard endpoints reflecting improvements in overall survival and quality-of-life measures, or containing strong site-specific evidence validating their use in order to demonstrate such improvements;
2. Grant market access via modified pathways and accelerated approval schemes in cases of unmet medical need, as intended, and prevent their misuse in cases where sufficient evidence for market approval is lacking;
3. Demand systematic collection and submission of real-world evidence (including overall survival, adverse reactions and quality-of-life improvements) once the medicine enters the market and its timely re-assessment, where appropriate.

iii. Review the regulatory framework for orphan and paediatric medicines

Orphan medicinal products (OMP) have become an attractive destination for investment thanks to the many incentives offered by the 2000 Orphan Regulation (e.g. scientific advice and protocol assistance with fee exemptions, orphan status and market exclusivity). Many new orphan medicines, ranging from products providing symptom management to curative solutions, have been introduced into the European market. However, it is necessary to note that 95% of rare diseases remain unaddressed. In addition, success with orphan medicine development has been largely overshadowed by the negative side effects of the Regulation’s IP protection on the affordability of these products.

The Paediatric Medicines Regulation, introduced in 2007, seeks to increase the licensing of medicines for children through a combination of incentives (such as 10 years of data and market exclusivity) and additional requirements for research into paediatric medicines (Paediatric Investigation Plan, PIP). It is widely acknowledged that there is a lack of new cancer drugs being developed specifically for paediatric populations relative to adults and that promoting additional investment in paediatric treatment options remains critical. For instance, for childhood cancers, the Regulation failed to achieve its desired impact, with only three paediatric-use marketing authorisations granted between 2007 and 2016. In addition, PIP waivers are granted too liberally as only two innovative cancer medicines were approved via PIPs between 2007 and 2016 [18]. While research suggests that around 50% of paediatric cancers could be treated with existing targeted drugs used in adults, only around 7% of paediatric patients receive these treatments [19]. However, these targeted drugs will not always be more appropriate than existing regimens.
While we await the European Commission's comprehensive evaluation of both orphan and paediatric medicine regulations, several issues with both legislative frameworks should be addressed by the Beating Cancer Plan and subsequently reflected in the legislations' review. These include:

1. Setting clear and transparent criteria for orphan designation at the time of marketing authorisation by the EMA based on significant benefit;
2. Preventing misuse and overuse of orphan status (including evergreening and salami slicing) and abuse of dominant market position by medicine developers;
3. Ensuring the right balance between investment in orphan medicine development, particularly where there exist no treatment alternatives, and preventing unintended effects on affordability (e.g. by revoking market exclusivity when a medicine has generated sufficient return on investment);
4. Introducing the ‘mechanism of action principle’ in the Paediatric Medicines Regulation to prevent the granting of PIP waivers when an adult cancer has no paediatric manifestation, even if the drug’s mechanism of action (such as targeting a specific genetic variation) could be plausibly beneficial for some paediatric cancers (e.g. lung cancer treatments), and so could reduce the ratio of waivers to PIPs in the long-run;
5. Introducing regulatory requirements and rewards for early PIP completion that will establish an evidence base for the paediatric population, even if the adult development program is aborted. Currently, new medicines showing promise for children are not adequately researched after a medicine fails to show potential for an adult indication;
6. Allowing for the inclusion of adolescents in paediatric phase I, II and III trials where relevant (e.g. for adolescents with paediatric cancer types or biological targets).

iv. Establish sustainable cooperation of health technology assessment (HTA)

HTA is an evidence-based process that independently and objectively assesses new or existing health products and compares them with other alternatives and standards of care. HTA is primarily used to inform decision-making in Member States by providing a scientific basis for decisions on pricing and reimbursement and contributes to the sustainability of national health systems. HTA further provides an incentive for innovation by rewarding technologies with high added value. There exists a strong connection between the implementation of robust European cooperation on HTA and access to high quality treatment for European patients, as recognised by the 2016 Council Conclusions on the functioning of the pharmaceutical system [20].
Adopting the European Commission’s legislative HTA proposal published on 31 January 2018 would: (i) improve timely access to high value treatments for patients in Europe; (ii) strengthen the quality of clinical assessment by pooling expertise from all EU Member States; (iii) reduce duplication and ensure efficient use of resources; (iv) help payers make wise reimbursement decisions; (v) increase clarity and transparency in the HTA process; (vi) steer innovation in areas of unmet medical need; and (vii) improve business predictability.

Europe’s Beating Cancer Plan should encourage the adoption of sustainable EU cooperation on HTA, while insisting on:

1. Closer cooperation between HTA bodies, the EMA and medicine developers to ensure submission of full data sets reflecting patient-relevant endpoints, including overall survival and quality-of-life measures;
2. A re-assessment of medical products once new data become available to get a clear understanding of their added value in real-life settings;
3. Meaningful involvement of patients, healthcare professionals, consumers, public health organisations and academia in the HTA process to get a clearer understanding of societal needs and preferences;
4. A transparent and independent assessment process promoting trust between assessors, Member States and stakeholders.

---

**v. Secure optimal essential medicines supply throughout the EU**

Recent studies by a number of European and national organisations have shown increasing problems caused by medicine shortages across the EU [21]. As a result, patients are at risk of suffering health deterioration if they cannot receive their prescribed medicines in a timely manner. This is particularly the case for patients taking medicines which have significant clinical consequences when doses are missed, including anti-cancer drugs. Shortages also cause financial implications for patients, leading to greater out-of-pocket expenses, as well as for health systems and hospital budgets (due to different reimbursement schemes for treatment alternatives).

Europe’s Beating Cancer Plan should include action by the European Commission on:

1. Investigating the causes of shortages of essential medicines and finding Europe-wide solutions which address supply chain and single market issues;
2. Assessing the consequences of drug shortages for cancer patients beyond direct costs or industrial processes;
3. Supporting further action on medicine shortages, together with the EMA and Heads of Medicine Agencies (HMA), considering the establishment of a joint action on medicine shortages in order to foster Member States’ cooperation, share good practices and set up an online information platform reflecting the up-to-date status of shortages across the EU;
4. Creating concrete and legally binding shortage management plans in order to switch from crisis management to an upstream approach.
With an aging population and a rising number of cancer cases in Europe, the expenditure on cancer medicines is growing. Lack of adequate access to both new and off-patent essential medicines remains an issue, with high prices often cited as a main contributory factor. Furthermore, overall prices of cancer medicines continue to rise, to the extent of impairing the capacity of health systems to provide affordable, population-wide access to treatments.

The medicines market is largely protected by a robust IP system related to the development and marketing of specific products. This prevents access to generics and biosimilars and keeps prices at a high level. Growing competition, particularly related to increased availability of biosimilars, significantly contributes to savings in medicine’s budget, allowing for both greater availability of off-patent medicines, but also greater investments in innovative treatment options.

The pharmaceutical industry often argues that high prices are connected to high research and development spending. However, it is widely recognised that: (i) medicine prices bear little or no relationship to R&D costs; (ii) financial returns on investment in cancer medicines are high (14 USD for every dollar spent); (iii) the potential impact on earnings due to lower prices could be offset by higher volumes, especially when the marginal cost of production is low; and (iv) governments and the non-profit sector have made substantial contributions to the pharmaceutical R&D through direct funding (grants, academic research) and other incentives (e.g. tax breaks) [22].

International collaboration between governments and all stakeholders is key to ensuring adequate access to medicines throughout the EU. Voluntary initiatives such as the Beneluxa and the Valetta Declaration contribute to knowledge-sharing on best practices in horizon scanning, HTA, and pricing and reimbursement. Setting a fair price as well as achieving the delicate balance between continuous innovation, patient access and the sustainability of healthcare systems is necessary.

Both Europe’s Beating Cancer Plan and the New Pharmaceutical Strategy for Europe should:

1. Recommend the continuous review of the European IP system (including the application of patent protection, SPC and R&D incentives) to ensure an effective stimulus for further innovation, particularly in areas of high unmet medical need, while avoiding the current affordability issues and excessive pricing spiral caused by anti-competitive practices (including pay-for-delay deals and misuse of patent protection and incentives);
2. Measure and disclose the extent of public investment in R&D at both the EU and Member State level and create the prerequisites for public investment in order to ensure that publicly funded products are available at an affordable price;
3. Foster collaboration between the EMA and national public health authorities, medical societies and patient organisations aimed at promoting trust in the uptake of and switching between biosimilar products, preventing any misinformation about their inferior quality;

4. Support the pooling of resources and international cooperation between EU Member States in order to prepare health systems for (i) the arrival of new medicines and technologies, (ii) conducting high quality HTA and sharing information about prices and pricing and reimbursement strategies, in order to enhance Member States’ ability to (a) prioritise medicines with higher clinical value, (b) review and adjust prices based on new evidence, and (c) effectively negotiate the prices of medicines;

5. Conduct a study on the role of price transparency, indicating ways forward to support the key elements of the WHO Transparency Resolution [23], with particular attention to robust state-of-the-art methods for the calculation of R&D and production costs in the pharmaceutical sector, and suggest ways forward toward EU-wide implementation of the WHO Transparency Resolution;

6. Establish a High-Level Working Group on fair pricing connecting all relevant stakeholders, including purchasers, patients, public health NGOs, academia and the industry in order to discuss the definition of a fair price and opportunities and challenges connected to different pricing models.

IV. SUPPORTIVE & PALLIATIVE CARE

i. Focus on patients’ quality of life and the integration of supportive care

The five-year prevalence of all cancers in the WHO Europe region, reached more than 12 million cases in 2018 [24]. As the number of cancer patients and survivors is growing, new challenges have arisen for both health and social protection systems in order to meet patients’ needs after diagnosis and treatment.

The 2008 Council conclusions on reducing the burden of cancer encouraged Member States to consider the psycho-social needs of patients and improve their quality of life through support, rehabilitation and palliative care. Yet timely systemic integration of the assessment of patients’ health-related quality of life (including physical, mental and social health) and the management of the multi-dimensional impact of cancer diagnosis and treatment as a vital part of long-term follow-up care is often neglected.

Comprehensive cancer care must include all actions that help patients to cope with the disease and ensure the best quality of life possible during and after treatment. Psychological support and the prevention and rehabilitation of chronic or late-onset side effects (e.g. fatigue, lymphoedema, chronic pain, cardiotoxicity or cognitive impairment) are a crucial part of supportive care offered to cancer patients and survivors.
Europe's Beating Cancer Plan should provide necessary support and encourage the exchange of best practice between Member States. In order to:

1. Ensure periodic psychosocial screening throughout the patient pathway and timely referral to specialised psychological care for both patients and their caregivers;
2. Ensure that prevention and rehabilitation of chronic and late side-effects of cancer treatment are an integral part of the treatment pathways of all cancer patients;
3. Advance the inclusion of psychological and social care for cancer patients and their family caregivers;
4. Secure funding, e.g. via Horizon Europe's Cancer Mission, for clinical research related to the prevention and management of the long-term side-effects of cancer treatment and the improvement of the quality of life for cancer survivors;
5. Provide adequate information and education for cancer patients in order to empower them and their families to increase their participation in health decision-making, self-management and rehabilitation.

**ii. Protect cancer patients and their families from the financial toxicity of cancer**

Cancer treatment poses an increasingly high financial burden on patients and their families. It is, therefore, critical to identify high-risk patients and provide them with the necessary support to overcome financial hardship during and after treatment. A study conducted in 2018 in Spain, found that family income decreases by at least 25% when one of the family members is diagnosed with cancer and that average monthly cancer-related expenses ranged between €150 and €300 [25]. A similar study in Ireland found that, on average, a cancer diagnosis meant an extra €862 a month in expenses and a loss of income of €1,400 [26].

Europe's Beating Cancer Plan should:

1. Strengthen the capacity of the European Agency for Health and Safety at Work (OSHA) to identify and work towards the implementation of best practices in national legislation providing security and flexibility for cancer patients and their caregivers in the workplace (including gradual return to work);
2. Encourage national governments to enable access to insurance and financial services for cancer patients and survivors, shaping national policies and implementing best practices, such as the right to be forgotten;
3. Ensure the full implementation of anti-discrimination laws with regard to citizens with medical disabilities, including the principles stated in the Anti-Discrimination and EU Equal Treatment directives;
iii. Ensure early integration of palliative care services

Palliative care is a holistic approach to patient care that aims to improve the quality of life of patients living with an incurable life-threatening chronic condition and that of their families and caregivers. Palliative care is fundamental to human dignity and a component of the human right to health. Palliative care is considered appropriate at any age and stage of the disease, regardless of the potential outcome, and can be provided alongside curative treatment. Thus, it concerns patients who require complex treatment, experience symptom burden and quality-of-life deficits and face prognostic uncertainty or a poor prognosis. Evidence suggests that early integration of palliative care can improve both patient and caregiver outcomes [27].

Europe’s Beating Cancer Plan should:

1. Encourage Member States to provide sufficient resources for timely palliative hospice and home care and to ensure equal access to these services across countries;
2. Ensure adequate training on palliative care is integrated in the curricula for healthcare professionals to better understand the use of palliative sedation for refractory symptoms, including the medical and ethical aspects.
REFERENCES