Cancer Leagues present
EUROPE'S BEATING CANCER PLAN
Towards better cancer control and care and closing the inequalities gaps 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 inequalities gaps throughout the EU. 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 them being the main source of information and services 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 a result of an extensive consultation process with ECL's members and focuses on key areas where Europe should work together to improve cancer control and care. It is not intended as a comprehensive blueprint for national cancer policy.

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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 the core to 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 inequalities 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 interventions’ impact in the long-term. Funding should be allocated to address unmet needs and close the inequalities gaps in cancer care. The approach to funding research should follow the same trends, as outlined by 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 Cancer Plan can ensure success.

- **Cross-sectoral 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 the effective dissemination and implementation of best practice across Europe. Bringing together and 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 have additional benefits both for other non-communicable diseases (NCDs). [5] Particular focus should be given to translating messages stated in the European Code Against Cancer (ECAC) [6] into European and national policy action.

i. Reduce use of tobacco and other nicotine products

Tobacco use remains a public health issue of the utmost importance. **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 trachea, bronchus 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 as 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 consider 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 allow 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.
**ii. Promote healthy lifestyle**

There is substantial evidence that an individual’s cancer risk can be reduced by adopting healthy dietary and physical activity behaviours. Excess body fatness is thought to increase the risk of 12 different cancer 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 bring forward proposals for the European Green Deal and the Farm to Fork Strategy, Europe’s Beating Cancer Plan should interact 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 (paying attention to 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 to restrict 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 injury risks. Ethanol and acetaldehyde from consuming alcohol are classified as a Group 1 carcinogens by the International Agency for Research on Cancer (IARC) and is **known to increase the risk of 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, 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 and certain places e.g., 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 of sunbed regulation from DG GROW to DG SANTE;
2. Investigate the potential to collaborate with Member States to phase out completely the use of sunbeds for cosmetic purposes, and implement other public health interventions suggested by the WHO [13];
3. Implement mandatory pictorial warning labels on the sunbed devices, stating ‘sunbeds cause cancer: even infrequent usage will increase your risk of skin cancer’;
4. Prohibit references to any supposed health benefits associated with using artificial tanning devices;
5. Increase market surveillance of sunbeds with strict enforcement protocols in compliance with age requirements on sunbed use and radiation limits;
6. Enhance 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 or during daily activities pose further risk factors. ECL calls upon the European Commission to develop tangible and impactful guidance and legislation to reduce citizen’s 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 measure to improve air quality in European urban spaces reflecting the latest WHO guidelines;
5. Ensure 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. Ensure Europe’s Beating Cancer plan is closely linked to a comprehensive EU Chemical’s Strategy for Sustainability and other chemical policy frameworks to rationalise and simplify EU’s chemicals and pesticides regulations for substances causing cancer; swift preparation of the long-overdue non-toxic environment strategy, as well as action to detoxify the circular economy.

vi. Enable population-wide access to vaccines

Few people associate infection 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 can cause most cervical and anal cancers as well as a fraction of oral cancers; hepatitis B virus (HBV) and hepatitis C virus (HCV), which 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 majority of cervical cancers.
Europe’s Beating Cancer Plan should propose measures to:

1. Become a leader in responding to WHO’s Global Call for Cervical Cancer Elimination as Public Health Problem, by supporting countries to reach the WHO’s HPV vaccination coverage targets for girls;
2. Investigate harmonisation of HPV and HBV vaccinations within Member States’ national vaccination programmes, ensuring equitable access;
3. Support further research into the most effective vaccination regimens against viruses associated with cancer (e.g., double and single dose);
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 on gender-neutral HPV vaccination strategies, considering potential global impact on vaccine supply.

**vii. Build capacity for early detection of cancer**

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 in early diagnosis by:

1. Scaling up the high-quality organised cervical cancer screening implementation in European countries with 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 the periodic implementation reports on cancer screening in the EU (ensure that the next implementation report on cancer screening is published before 2024);

5. Collaborate 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. Build capacity across Europe for early detection by 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 to exchange of experience, knowledge and best practices. Establish 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;

7. Develop 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 interventions accelerate significantly through research. Comprehensive and unbiased population-level analyses are essential to provide sound evidence about risk factors for disease, public health and the effectiveness of healthcare systems. Therefore, research efforts are conditioned by the possibility of sharing high-quality individual health data across the EU, European Economic Area (EEA) and as part of global collaborations.

The General Data Protection Regulation (GDPR) acknowledged the need for addressing the current and future health challenges by collecting and sharing health data in an ethical manner. However, many challenges remain to fully benefit from the free flow of such data for research purposes within and outside of the EU.

In addition, further structural investments are necessary to ensure the interoperability of national cancer registries, 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 for rare cancers, further enabling linkage with other data sources (including digital health records, medical prescriptions, Clinical Patient Management System (CPMS), biorepositories);
2. Supporting national cancer registries in capacity building and 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 survivorship;
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 of the EU (including EEA and the UK);
4. Investigating the best means to securely share high quality aggregate health data for scientific research and quality control, by promoting research into new anonymisation technologies, such as homomorphic encryption and synthetic data, to fulfil the needs for high quality research in a cross-border setting.

Europe’s Beating Cancer Plan 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, recently published report of the European Court of Auditors showed the Directive’s benefits for patients were 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 about their rights to seek cross-border healthcare. It is important to note that while fostering cross-border care for cases which require special treatment, such as 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, 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.

ii. Facilitate implementation of Cross-border Healthcare Directive and growth of European Reference Networks (ERNs)
As rare cancers form 24% of all cancer across Europe, any cancer control strategy must also include specific action on rare cancers. [14] Therefore, Europe’s Beating Cancer Plan should:

1. Support the capacity and capability of NCPs on how to communicate the relationship between the Cross-border Healthcare Directive and the Social Security Coordination Regulation pathways, to ensure patients receive clear information about their rights, possibilities and insurance coverage and to raise awareness of opportunities for patients’ access to clinical trials in other countries;
2. Ensure NCPs have been established in each EU Member State and that they follow the advice of competent ERNs to facilitate transfer of rare cancer patients to another EU country;
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 that each Member State has at least one full or affiliated member of ERNs 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 an additional layer (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 implemented in the correct way, it could represent a partial solution to some of the challenges (e.g., shortages) while also developing a workforce with larger skills sets, enhanced flexibility and ability to address future challenges.
If we are to reduce inequalities in access and quality of care in the EU, moving towards interoperability and European initiatives (e.g., the European Health Data Space, 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 ultimately overcoming staff shortages. Particular attention should be given to underappreciated professions such as oncology nurses, radiotherapy trained staff and palliative care specialists;
2. Amplifying of 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 to 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

e. Foster European collaboration in clinical research

Clinical trials are the gold standard for testing treatment’s efficacy and safety. Not only do they help drive progress in cancer research, but they also afford vital opportunities to 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 of the current Clinical Trials Directive, harmonising the regulatory environment for clinical trials across the EU, to benefit of both patients and researchers. It will allow for 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 significantly 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 professional to identify and financially support areas of unmet medical need and low financial interest;
4. Making research results and data set of all clinical trials submitted to the EMA for marketing authorisation publicly available, in order to build trust in EU's regulatory framework and fosters further research about the product's efficacy and safety;
5. Compelling public and private research entities to abide to the WHO Joint statement on public disclosure of results from clinical trials [16] as timely disclosure leads to reductions of waste in research, increases value and efficiency in use of funds and reduces reporting bias, which ultimately leads to better decision-making in health.

ii. Ensure robust regulatory environment for medicines’ approval

The European Medicines Agency (EMA) evaluates the efficacy and safety profile of medicines. However, as data from clinical trials used for the EMA assessment 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 speed up access in areas of high unmet medical need. [17] It is questionable, whether early access schemes are used as intended, or 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 of medicines, stressing the need for surrogate endpoints in clinical trial to be accompanied by hard endpoints reflecting improvements in overall survival and patient's quality of life measures, or have strong site-specific evidence validating their use to demonstrate such improvements;
2. Grant market access via adaptive 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 (re overall survival, adverse reactions and quality of life improvements) once the medicine enters the market and its timely re-assessment, where appropriate.

iii. Review regulatory framework for orphan and paediatric medicines

Orphan medicinal products (OMP) have become an attractive destination for investment and 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, were introduced to the European market. Though, it is necessary to note that 95% of rare diseases remain unaddressed. In addition, success in orphan medicines development has been largely overshadowed by the negative side effects of regulation's IP protection on affordability of these products.

The Paediatric Medicines Regulation, introduced in 2007, seeks to drive 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] Although, these targeted drugs will not always be more appropriate than existing regimens.
While we are awaiting the European Commission’s comprehensive evaluation of both orphan and paediatric medicines 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 sustaining orphan designation at the time of marketing authorisation by the EMA based on significant benefit;
2. Preventing misuse and overuse of the orphan status (incl. evergreening and salami slicing) and abuse of dominant market power by medicines developers;
3. Ensuring the right balance between investment in orphan medicines development, particularly where there exist no treatment alternatives, and preventing unintended effects on affordability, e.g., by revoking market exclusivity when medicine generated sufficient return on investment;
4. Introducing the ‘mechanism of action principle’ in the paediatric regulation to prevent granting of PIP waivers when an adult cancer has no paediatric iteration, even if the drug’s mechanism of action (such as targeting a specific genetic variation) was 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 in 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 type 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 base 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 strong connection between implementation of a robust European cooperation on HTA and access to high quality treatment for European patients, as recognised by the 2016 Council Conclusions about the functioning of the pharmaceutical system. [20]
Adopting the European Commission’s legislative proposal HTA 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 medicines developers to demand submission of full data sets reflecting patient-relevant endpoints, including overall survival and quality of life measures;
2. Re-assessment of medical products once new data become available to get a clear understanding of its added value in the real-life settings;
3. Meaningful involvement of patients, healthcare professionals, consumer, public health organisations and academia in the HTA process to get a clearer understanding on 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 medicines 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 a significant clinical consequence 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 health systems and hospital budgets (due to different reimbursement schemes for treatment alternatives).

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

1. Investigating the causes of shortages of essential medicines and find European-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 medicines shortages, together with the EMA and Heads of the Medicines Agencies (HMA), considering the establishment of a joint action on medicines shortages in order to foster Member States’ cooperation, share good practices and aim to set up an online information platform reflecting current shortages status in the EU;
4. Creating concrete and legally binding shortage management plans in order to switch from crisis management to an upstream approach.
vi. Increase European efforts to achieve affordable access to high quality treatments for cancer patients

With an aging population and 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.

Medicines market is largely protected by robust IP system related to 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 medicines budgets, allowing for both greater availability of off-patent medicines, but also greater investments in innovative treatment options.

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 with R&D costs; (ii) financial returns on investment in cancer medicines are high (14 USD for every dollar spent); (iii) the potential impact on revenue 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 R&D of medicines through direct funding (grants, academic research) and other incentives (e.g., tax breaks). [22]

International collaboration between governments and all stakeholders is key for ensuring adequate access to medicines throughout the EU. Voluntary initiatives such as 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 sustainability of healthcare systems is necessary.

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

1. Recommend continuous review of European IP system (including application of patent protection, SPC and R&D incentives), to ensure effective stimulus for further innovation, particularly in areas of high unmet medical need, while avoiding the current excessive pricing spiral caused by anti-competitive practices (incl. pay-for-delay deals and misuse of patent protection and incentives) and affordability issues;
2. Measure and disclose the extent of public investment in R&D at both the EU and Member State level and create prerequisites to public investment in order to ensure that publicly funded products are available for an affordable price;
3. Ensure close collaboration between the EMA and national public health authorities, medical societies and patient organisations about promoting trust in the uptake of and switching between biosimilar products, preventing any misinformation about their inferior quality;
4. Support pooling of resources and international cooperation between EU Member States in order to prepare health systems for the arrival of new medicines and technologies, conducting high quality HTA and sharing information about prices and pricing and reimbursement strategies, in order to enhance the Member State’s ability to prioritise medicines with higher clinical value, review and adjust prices based on new evidence, and effectively negotiate medicines prices;
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 state-of-the-art and robust 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 payers, 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 integration of supportive care

The five-year prevalence of all cancers in the WHO Europe region, accounted for more than 12 million 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 the 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 health-related quality of life (including physical, mental and social health) and the management of the multi-dimensional impact of cancer diagnosis and treatments as a vital part of long-term follow-up care, is often neglected.

Comprehensive cancer care must include all interventions that help patients to cope with the disease and to ensure the best quality of life possible during and after treatments. Psychological care and the prevention and rehabilitation of chronic or late-onset side effects such as 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 exchange of best practice between Member States. Particularly to:

1. Ensure periodic psychosocial screening throughout the patient pathway and timely referral to specialised psychological intervention for both patients and their caregivers;
2. Ensure that prevention and rehabilitation of the chronic sequelae and late side-effects of cancer treatments are integrated in the treatment pathways of all cancer patients;
3. Advance integration 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 long-term side-effects of cancer treatments and interventions improving the quality of life of 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 treatments pose 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 hardships during and after treatment. A study conducted in 2018 in Spain, found that family income decreases by at least 25% when one of the members is diagnosed with cancer and average monthly expense ranged between €150 and €300. [25] A similar study in Ireland found that on average, 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 flexibilities for cancer patients and their caregivers at 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 full implementation of anti-discrimination law in regard to citizens with medical disabilities, including 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 for patients, and their families, living with an incurable life-threatening chronic condition, such as cancer. 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 eventual outcome, and can be provided along with curative treatment. Thus, it concerns patients who require complex treatment, experience symptom burden and quality of life deficits, while facing prognostic uncertainty or 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 ensure equal access to these services across the country;
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 medical and ethical aspects.

The Association of European Cancer Leagues (ECL) is a non-profit, European umbrella organisation of national and regional cancer societies. Located in Brussels, ECL provides an exclusive platform for members to collaborate with their international peers, primarily in the areas of cancer prevention, tobacco control, access to medicines and patient support, and creates opportunities to advocate for these issues at the EU level.

VISION: A Europe free of cancers
MISSION: To advocate for improved cancer control and care in Europe through facilitating collaboration between cancer leagues, and influencing EU and pan-European policies.

www.cancer.eu @CancerLeagues #EUCancerPlan

Wish to further discuss ECL’s vision for Europe’s Beating Cancer Plan?
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REFERENCES