TIME TO ACCELERATE FOR EUROPE
TOGETHER AGAINST CANCER

EUROPEAN CANCER MANIFESTO FOR 2024

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#EUCancerManifesto
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THE EUROPEAN CANCER CHARTER 2024

Summarising the Time to Accelerate Manifesto, the following Charter is put forward to all EU decision-makers ahead of the upcoming European elections:

Deliver in full, the promise and potential of Europe’s Beating Cancer Plan and the EU Research Mission on Cancer, through 2024 and to 2030 and beyond
The goals, projects and foundations brought about by the publication of Europe’s Beating Cancer Plan and the EU Research Mission on Cancer must be seen through to completion, not left half done. Political and stakeholder commitment must be renewed and strengthened.

Refresh Europe’s Beating Cancer Plan and the EU Research Mission on Cancer
The world has not stood still since 2021. Factors indicating the value of update include: growing science and practice developments in fields such as hereditary cancer understanding, multi cancer early detection and personalised medicine; and the too-long unaddressed experience of ongoing chronic workforce shortage within oncology systems across Europe.

Expand the pan-European goal-orientated approach to cancer control
Setting clear goals in any field of activity gives clarity, certainty, accountability and unites diverse stakeholders via a common aim. In the context of European cancer policy it can also serve as a vital mechanism for addressing inequalities in cancer care that exist between and within countries.

Progress towards existing EU goals in areas such as HPV cancer elimination, the achievement of a tobacco free generation, access to screening programmes and comprehensive cancer care, should be reported upon and published annually to accelerate momentum towards their achievement.

New goals should be agreed by the European Commission, Parliament, and Member States. Suggestions include: an average of 70% ten-year survival rates for all European patients with cancer by 2035 (the “70:35” vision¹) and, allied to this, a doubling of survival for poor prognosis tumours².

Make Europe a global leader in the fight against cancer
Rising incidence of cancer is a global challenge. With the foundations of Europe’s Beating Cancer Plan and the EU Research Mission on Cancer, there is now opportunity for the EU to give leadership at world level. Chances to synergise global efforts, such as the WHO goal of cervical cancer elimination and connecting EU cancer efforts with US Cancer Moonshot endeavours, should be actively pursued.

Address Europe’s oncology workforce crisis
Taking inspiration from the new commitments at EU level to combatting health product and medicine shortages as a collective endeavour across countries, the new European Commission 2024–29 should set shared goals and conduct initiative to combat the persistent and growing crisis of shortage in the oncology and health professions experienced by all EU countries.

We encourage all who support the European Cancer Charter and Time to Accelerate Manifesto to share their endorsement via manifesto@europeancancer.org
Foundations laid, communities of cooperation created, but a job still to be finished

“Time to Accelerate: Together Against Cancer” is duly presented as a manifesto of recommendations for the future of EU cancer policy under the next European Commission 2024-2029.

It represents the result of inputs and consultations with a large number of organisations and individuals active in pan-European cancer policy cooperation, and specific consultation with the Focused Topic Networks of the European Cancer Organisation (ECO). We especially thank the member societies of ECO and the ECO Patient Advisory Committee for additional scrutiny of suggestions during the policy approval pathway consultation which took place on the full draft.

The Time to Accelerate manifesto recommendations reflect experiences and perspectives gathered during an unprecedented five-year period in EU cancer policy, with landmark attention and investment provided via both Europe’s Beating Cancer Plan and the EU Research Mission on Cancer.

Time to Accelerate salutes and congratulates EU Member States and the European Commission for the commitment both initiatives represent, and the hope they offer in bringing about a new era of cross-border cooperation in cancer care.

But this promise for the future must not be diminished or extinguished by any rush towards new agendas and alternative prospectuses under a new European Commission. The seeds only so recently planted by Europe’s Beating Cancer Plan and the EU Research Mission on Cancer must be nourished to full growth. Political commitments should be refreshed. We must continue to acknowledge and respond to gaps, fresh needs and the ever-present advances in science, practice and technology in our European cancer community.

Time to Accelerate is thus conveyed as a core contribution to that discussion and response. We invite all who find its recommendations worthy of active support to join the European cancer community in advancing their uptake.

Find out more and join the campaign at europeancancer.org/manifesto
1. No letting up: the cancer prevention opportunities in our hand

Cancer prevention: the most cost-effective cancer policy

With 30–50% of all cancer cases being prospectively preventable, there can be little doubt that strong cancer prevention policy offers the most cost-effective long-term strategy for the control of a number of cancers. The primary leading risk factors are well known, yet most still lack appropriate policy response.

27% of all cancer cases in Europe are attributable to tobacco consumption. It has been proven that smoking can cause cancer in at least fifteen parts of the body: nose, mouth, voice box, throat, gullet, lung, liver, stomach, kidney, pancreas, bowel, ovary, bladder, cervix, and bone marrow. It is estimated that by eliminating tobacco use, nine out of every ten cases of lung cancer could be avoided.

After tobacco, a further leading cause of cancer in Europe is alcohol consumption. A comprehensive study on risk factors for cancer in France found only tobacco smoking was reported to cause higher cancer incidence than alcohol. Alcohol is associated with seven major types of cancer, including breast, liver, and colon cancer. Although alcohol was classified as a Group 1 carcinogen by the International Agency for Research on Cancer decades ago, Europe remains the continent with the highest alcohol consumption in the world. As advised by the WHO, there is no safe level of alcohol intake, the latest available data indicate that half of all alcohol-related cancers in the WHO European Region are caused by “light” and “moderate” alcohol consumption (less than 1.5 litres of wine or less than 3.5 litres of beer or less than 450 millilitres of spirits per week).

Other lifestyle factors, including diet sitting time, level of physical activity and body composition, have long been recognised as determinants in cancer risk. Prospective studies have shown that dietary patterns characterised by higher intakes of fruits, vegetables, and whole-grain foods, and lower intakes of red and processed meats and salt, are related to reduced risks of death and cancer, and that a healthy diet can improve overall survival after diagnosis of breast and colorectal cancers. There is evidence that high intakes of fruit and vegetables may reduce the risk of cancers of the aerodigestive tract, and the evidence that dietary fibre protects against colorectal cancer is convincing. Red and processed meats increase the risk of colorectal cancer.

There is strong evidence that higher levels of physical activity are linked to lower risk of several types of cancer. These cancers are bladder, breast, colon, endometrial, kidney, and gastric.

Furthermore, the European Environment Agency calculate that exposure to air pollution, carcinogenic chemicals, radon, UV radiation and second-hand smoke together may contribute over 10% of the cancer burden in Europe.

Europe’s Beating Cancer Plan and cancer prevention: the strongest section

It was evident immediately on publication that the most robust section of Europe’s Beating Cancer Plan, in terms of intention and ambition, related to cancer prevention. With many legislative tools at hand, including in respect to tobacco, alcohol and food regulation, important elements of goal-oriented vision were expressed. Backbones of the cancer prevention section include commitments on achieving:

- a tobacco free generation, where less than 5% of the European population uses tobacco by 2040;
- reviews of both the Tobacco Products and Taxation Directives;
- an updated Council Recommendation on smokefree environments;
- a review of EU legislation on the taxation of alcohol;
- legal proposals for (a) a mandatory labelling of the list of ingredients and nutrition declaration on alcoholic beverage products; and, (b) health warnings on alcoholic beverage products;
- a legal proposal for mandatory front of pack nutrition labelling for food products;
- alignment of EU air quality standards more closely with WHO guidelines;
- new EU limits to asbestos exposure;
- exploration of measures to reduce ultraviolet radiation exposure, including from sunbeds;
- an update, and boost to the implementation of, the European Code Against Cancer; and,
- the implementation of pan-European health promotion projects such as HealthyLifestyle4All.

Every one of these initiatives in Europe’s Beating Cancer Plan is strongly supported by the European cancer community. However, progress on many of these commitments has not always been able to keep to time or ambition, with factors of frustration including strong industry lobbying against such measures as front of pack nutritional labelling for food products, or the provision of consumer health warnings on the packaging of alcohol beverage products.
The European Cancer Organisation calls for consumer health and the public interest to triumph over narrow producer concerns. Our recommendations follow.

**Time to accelerate the prevention of cancer**

The achievement of a tobacco free generation in Europe should be accelerated by:
- working towards an agreed pan-European minimum age for tobacco sales of 21 (‘tobacco 21’) and encouraging Member States to ban sales and delivery of tobacco products to a person born after 1 January 2012 to achieve a tobacco free generation by 2040;
- delivering new regulation to protect citizens from second-hand smoke in outdoor locations (playgrounds, restaurants, beaches);
- bringing the taxation of novel tobacco and nicotine products into line with cigarettes and increasing minimum taxes rates on cigarettes and fine cut tobacco;
- banning flavours in both tobacco and vaping products and prohibiting flavour accessories and additives;
- strengthening packaging rules by introducing mandatory plain standardised packaging, with graphic health warnings covering 80% of the front and the back of all tobacco products, and introducing pack inserts; and,
- every World No Tobacco Day to be marked by an annual report from the European Commission on the progress of the EU towards achieving a tobacco free generation.

To support citizens in being better informed in their dietary choices, the promises of Europe’s Beating Cancer Plan should be kept. This means achieving EU regulation requiring:
- mandatory front-of-pack nutrition labelling for food products, using an intuitive colour-coded scheme; and,
- mandatory health warning labels on alcoholic beverages to help inform consumers of the association between alcohol intake and cancer risk.

To bring about the promise of Europe’s Beating Cancer Plan in reducing cancers related to air pollution:
- EU funding support should be leveraged to help enhance the monitoring and measurement of air pollution levels across Europe; and,
- Further research should be supported into understanding and expressing the wider health and economic costs of air pollution.

To support the achievement of the new EU limits on asbestos exposure:
- A public monitoring mechanism should be established to underpin implementation of new EU asbestos limits;
- EU level guidelines should be developed to help advise and support countries in:
  - best conducting asbestos screening; and,
  - creating and maintaining interoperable asbestos registers.

To prevent cancers caused by ultraviolet radiation exposure:
- Sunbeds should be regulated as medical devices and their use phased out for aesthetic purposes.
- EU wide public awareness campaigns should be implemented on UV exposure risk, including placing an emphasis on the protection of children and teenagers during organised recreational activity, and outdoor workers.
- UV exposure should be regulated as an occupational carcinogen under EU law.

An under-addressed matter in respect to cancer prevention and causation within the 2021 Europe’s Beating Cancer Plan is related to hereditary causation of cancer. This is a valuable area of cancer policy for investment both in respect to research and also in response. Hereditary cancer risk counselling remains a severely under met need across Europe with prospective support from programmes such as EU4Health offering significant prospect for achieving greater pan-European response.

Furthermore, EU investments in health promotion campaigns and projects should be maintained and be underpinned by much needed studies into the socio-economic benefits of governmental investment in prevention services initiatives.
Prevent what is preventable: the case for HPV and HBV cancer elimination

HPV (human papillomavirus) is a very common sexually transmitted infection that causes 4.5% of all cancers in women and men worldwide. In the European continent, about 2.5% of cancers are attributable to HPV. The virus causes more than just cervical cancer. It is also responsible for a high proportion of anal, penile, vaginal, vulval and oropharyngeal cancers. The virus is also responsible for genital warts and recurrent respiratory papillomatosis (RRP). Based on 2020 estimates for Europe, over 58,000 new cases of cervical cancer and 14,700 anogenital cancers, excluding cervical, can be attributed to HPV infection.

HPV affects people of all genders. Between 20 and 40% of cancers related to HPV are in men and men are more likely than women to have a high-risk (i.e. cancer-causing) HPV infection. Almost one in three men worldwide are infected with at least one genital HPV type and around one in five men are infected with one or more HR-HPV types. Infection rates are even higher in men who have sex with men.

Meanwhile, based on data from 2015, it is estimated that across the EU/EEA and the United Kingdom, Hepatitis B (HBV) and Hepatitis C (HBC) are responsible for approximately 55% of all liver cancer deaths and 45% of all deaths due to cirrhosis and other chronic liver disease and result in approximately 64,000 deaths annually. Yet all health systems can stem these numbers if implementing effective Hepatitis B (HBV) vaccination policies, alongside WHO recommended policy interventions for Hepatitis C. Chronic Hepatitis C is the primary cause of liver cancer in Europe.

However, vaccination rates in Europe, and elsewhere, currently vary widely, for both HPV and HBV. For example, according to the limited data available for the European region, only seven countries achieved over 80% uptake of girls receiving all their HPV vaccine doses. While several managed over 70% uptake, other countries had coverage rates of below 50%. Still in the European Union 5 Member States are yet to include boys in their national immunisation programmes for HPV vaccination. There are also in-country variations in uptake linked to socio-economic status, ethnicity and religious beliefs. For instance, important data on inequalities show Dutch girls with parents born in Morocco are only half as likely to have received the HPV vaccine as those whose parents were born in the Netherlands.

For hepatitis B, while the vaccine tool is widely recognised for its prevention effectiveness, still only 50% of EU/EEA countries with universal childhood vaccination have reached the target of 95% hepatitis B vaccination coverage. Too often as well, the HBV vaccination is not made available as part of national healthcare coverage. Yet this is vital if target populations are to be effectively addressed, including newborns and children, migrants, people who inject drugs (PWID), people in prisons, people living with HIV, and men who have sex with men (MSM).

Beyond vaccination, long standing recommendations at an EU level that support the elimination goals are still to be taken up in all countries. This includes EU guidelines for population level cervical cancer screening, making use of HPV-DNA testing to increase the quality of screenings in detecting the presence of HPV. Encouragement should also be given to the use of self-sampling as a screening option that can increase convenience and improve access and reach.

Opportunities are also recognised to improve policy response in respect to screening for anal pre-cancers, mostly caused by HPV. This is particularly important for people with a previous HPV cancer. Women with a high-grade cervical pre-cancer are at higher risk of vulval, vaginal and anal cancers, for example. Anal cancer screening is also relevant to people with HIV who are also at much higher risk of anal cancer than the general population.

The opportunities recognised: Europe’s Beating Cancer Plan

On publication, one of the highlights of Europe’s Beating Cancer Plan was a very clear commitment, in its early pages, to a significant landmark goal: to eliminate cervical cancer and other cancers caused by human papillomaviruses. This was accompanied by the stated objective to vaccinate at least 90% of the EU target population of girls and to significantly increase the vaccination of boys by 2030. The achievement of the goal is now being supported by several EU4Health initiatives, including:

- **PROTECT-EUROPE**: a pan-European consortium of 33 expert stakeholder organisations, from 16 member states, building common tools and approaches for every country to deploy in advancing the EU goal of HPV cancer elimination.
- **Joint Action PERCH**: 18 European government agencies and many others collaborating to improve the capacities of Member States in planning and implementing HPV vaccination, including...
improving data and monitoring system on HPV vaccination and HPV screening; improving knowledge and awareness on HPV-related disease and prevention in specific target groups; and improving knowledge and abilities for healthcare professionals in HPV vaccine communication.

- **ReThinkHPVaccination**: The #ReThinkHPVaccination Project aims at reducing inequalities in HPV vaccination between and within countries through personalised communication and training, based on social innovation and assessment, as well as targeted interventions on the behavioural determinants of health. The project supports Romania and other CEE countries to rethink, restart or begin their HPV vaccination campaigns and so take a step closer to achieving the WHO objective and Europe’s Beating Cancer Plan and Cancer Mission objectives with regards to HPV vaccination and cancer prevention.

Additionally, the Horizon Research programme is supporting the RIVER-EU (Reducing Inequalities in Vaccine uptake in the European Region – Engaging Underserved communities) project to improve access to HPV vaccination services for children and adolescents in selected underserved communities, such as migrant, refugee and the Roma community.

The HPV cancer elimination goal has also inspired many other relevant European level initiatives including the publication of the [EPF/ECO HPV Policy Atlas](#) which was launched in June 2023 and provides a detailed overview of the current state of HPV prevention policies in Europe. It provides a valuable resource for policymakers and stakeholders at national level in considering the available policy options that will drive the most impactful changes in their countries, and improve outcomes at a population level.

While data is key to drive public health policy decision-making, major gaps exist in Europe with very few European countries having robust electronic vaccination and cancer registries. Lack of standardisation in data collection as well as interoperability in systems that are in place within and across Member States make it impossible to have a timely overview of where the EU27 stands today in relation to the EC flagship initiative on the elimination of HPV related cancers.

Some reservations have also been expressed that Europe’s Beating Cancer Plan did not make as ambitious a statement towards achieving the elimination of vaccine preventable cancers as it might have. Further ambition might have been expressed by, for example, committing to the achievement of gender-neutral HPV vaccination in all countries, recommending an equal vaccination target (at 90%) for males and females, and stating an allied goal for HBV cancer elimination. It is to be hoped that the forthcoming Council Recommendation on vaccine-preventable cancers may address these known gaps.

### Finishing the job: the next actions towards elimination achievement

#### Debunking myths and disinformation around vaccination.

Accelerating the elimination of vaccine-preventable cancers requires:

Enhancing EU level action against misinformation and disinformation about vaccination on social media;
- Urging Member States to formally endorse, and express shared support for, the EU Code of Practice on Disinformation and commit together to long term support of its application, including via rigorous enforcement of the new Digital Services Act, and funding for impact related research;
- Recommending EU Member States to keep working in close cooperation with online platforms to encourage them to promote authoritative sources, demote content that is fact-checked as false or misleading, and take down illegal content or content that could cause physical harm; and,
- Gathering good practices, including activities and communications campaigns to fight anti-vaccine infodemics taking place in countries across Europe and internationally.

**Annual monitoring and reporting publicly on progress towards eliminating HPV and HBV cancers across Europe**

Tools should be enacted to improve monitoring and reporting towards HPV and HBV cancer elimination, including:

- **Urging** an agreement by EU Member States to mandate the European Centre for Disease Prevention and Control to put in place a monitoring system for HPV and HBV vaccine uptake across the EU (similar to systems created during the COVID-19 pandemic for real time vaccine uptake information – the “COVID19 vaccine tracker”);
- Helping EU Member States to achieve greater commonality in national immunisation registry systems to support timely monitoring and tracking, ensuring data-driven decision-making; and,
- Reporting on other indicators of success and progress, including:
  - vaccination rates according to indicators such as primary, catch-up cohorts, and adult and at-risk groups;
• Accessibility to vaccination programmes, including locations from which vaccination can be obtained (e.g. schools, pharmacies, etc);
• Cervical cancer screening access and uptake rates, and the type of tests used;
• Public awareness about HPV and HBV; and,
• Indicators related to the fight against disinformation.

**Accelerating the achievement of HPV cancers elimination through gender-neutral vaccination**

• Via the forthcoming EU Council Recommendations on vaccine preventable cancers, a fresh shared commitment by EU Member States should be established to achieve together the goal of HPV cancer elimination, as contained in Europe's Beating Cancer Plan and via the WHO Cervical Cancer elimination strategy.
• This commitment should clearly indicate that the goal of HPV cancer elimination should be achieved by policies of gender-neutral vaccination in all countries with a target vaccination rate of 90% for everyone.

A further range of suggestions for inclusion in the upcoming EU Council Recommendations on vaccine preventable cancers is available here. In a constantly developing field of scientific understanding, other matters meriting consideration include potential policy response to emerging evidence of the value of vaccinating women with preinvasive disease.

**Allying the goals of HPV and HBV cancer elimination**

• All EU Member States should be recommended to provide free HBV vaccination, as part of national healthcare coverage.
• Every EU Member State should be strongly encouraged to implement strategies to increase HBV vaccination coverage for newborns, children, and risk-groups.
• HBV vaccination programmes should be targeted to ensure key adult populations receive coverage, including migrants, people who inject drugs, people in prisons, people living with HIV, gay, bisexual, and other men who have sex with men, and healthcare workers.
3. Earlier saves lives: the rights of citizens to better early detection policies

Early detection of cancer: a field of increasing options and opportunity

For those cancers that can have more possibility to be detected and diagnosed at an early stage – before it becomes advanced and metastatic – benefits include:
• greatly increasing the chances of treatment being successful, in many cases providing the chance for curative treatment;
• enabling a greater range of treatment options to be available, including less invasive and toxic treatment, with lower risks and impacts on quality of life;
• providing opportunity for more straightforward and less expensive treatment options; and,
• preventing more severe symptoms and complications associated with a cancer from arising.

Policies that can help achieve earlier detection of cancer include:
• access to, and uptake of, cancer screening programmes;
• improving awareness of the early warning signs and symptoms of cancer,
• ready access to healthcare services, including capacity building in primary care, to enable prompt medical attention for any such concerns; and,
• monitoring those groups at higher risk of developing cancer, such as people living with hepatitis B and hepatitis C.

Additionally, the field of cancer detection is undergoing several scientific, technical and practice revolutions simultaneously. This includes:
• better tailoring and performance of screening programmes, including risk-based programmes for screening cancers such as lung cancer, prostate cancer and gastric cancer;
• updates to the technologies deployed to conduct screening for cancers such as breast, colorectal and cervical cancer, including new means to improve access such as self-sampling;
• increasing understanding about an individual’s prospective genetic disposition to cancer;
• the use of Artificial Intelligence to speed up and enhance detection and diagnosis of cancer; and,
• growing availability of new technologies such as liquid biopsy and other biomarkers, and the promise of multi cancer detection technologies and genomic tumour testing to improve both detection and the pathway to more effective treatment.

Early detection of cancer: taking the pulse on inequalities

As across many areas of cancer care, analysis of available data sheds a picture of some significant inequalities in early detection of cancer policies across Europe. The following statistical analysis and selected snapshot is taken from the European Cancer Pulse, with source data from Eurostat.

<table>
<thead>
<tr>
<th>Country</th>
<th>Indicator</th>
<th>Value</th>
<th>Year</th>
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**Re-balancing the EU early cancer detection agenda**

When considering the breadth of need in early detection of cancer, it is the reflection of many that EU cancer policies have so far comparatively neglected needs supporting early cancer detection for the many tumour types not covered by cancer screening policy – which are, indeed, the majority of tumour types.

A rebalancing and refresh of EU cancer policy is therefore called for to better pick up on such opportunities as:
- improving population health literacy about early warning signs of cancer;
- leveraging the full potential of newer areas of science and understanding such as hereditary cancer risk;
- supporting the use of artificial intelligence within early detection and diagnosis programmes to assist in accuracy and efficiency; and,
- more recently available tools such as liquid biopsy and multi-cancer early detection tests.

**Time to accelerate: for early detection of cancer**

To fulfil the commitments of Europe’s Beating Cancer Plan on cancer screening, under the next European Commission 2024-2029, it is recommended that fresh actions be taken to:
- raise awareness of the EU Council recommendations on cancer screening and their content at national level in order to stimulate political action on their achievement;
- bring about regular public reporting on the progress towards implementation of the Council Recommendations on cancer screening, celebrating and sharing success and improvement in screening policy and outcomes when they occur;
- utilise, and sustain, implementation-focused projects at regional, national and international levels to support countries in achieving the EU Council Recommendations’ expanded advice on cancer screening programmes;
- provide support for new screening research endeavours in fields such as: behavioural insights, inequalities access and participation in screening, the health economics of screening, and screening methodologies relevant to other cancer types such as skin and liver cancer;
- give attention to evidentiary frameworks for the use of multi cancer early detection tests; and,
- facilitate the process for all countries to provide robust data infrastructure associated to screening programmes, and to common standards to enable ready comparability, and the provision of new insights e.g. HPV genotype information in respect of cervical cancer screening.

To balance, and make comprehensive, EU policy on cancer screening, it is recommended that:
- the growing science, understanding and support tools available in respect to hereditary cancer risk be recognised. This should include:
- promoting an increase in availability of hereditary cancer risk support tools and services at national level, including via EU4Health and Horizon Research project funding (e.g. to support oncology professional upskilling on this topic).
• monitoring citizen and patient access to counselling on their hereditary cancer risk as part of the European Cancer Inequalities Registry41.
• Within the Horizon Europe programme, and its EU Research Mission on Cancer, attention should be focused on supporting the research agenda connected to the use of liquid biopsy for early detection of cancer, and multi cancer early detection testing more generally.
• In emulation of the highly successful European Code Against Cancer for improving health literacy about cancer risk and prevention, an accompanying EU Atlas of Early Warning Signs of Cancer should be commissioned for development and dissemination.
4–Comprehensive quality cancer care for all

Quality Cancer Care: multi-professional care in action

Quality cancer care is at the heart of the European Cancer Organisation’s guiding mission: “To reduce the burden of cancer, improve outcomes and the quality of care for cancer patients, through multidisciplinarity and multiprofessionalism”42.

Concepts of quality cancer care are also well expressed through the European Code of Cancer Practice43, including its stated rights of cancer patients:

- to equal access to affordable and optimal cancer care (Right 1);
- to information about the quality of and safety of care, levels of expertise, and outcomes in the centres where cancer patients are treated (Right 3); and,
- to receive care from a specialised multidisciplinary team, ideally as part of a cancer network (Right 4)

As such, with the involvement of so many components, the question of achieving quality cancer care is intimately related to the structures and processes of cancer care delivery. With this in mind, the European Cancer Organisation has been working with oncology professional societies, patient organisations, and leading associations such as the Organisation of European Cancer Institutes (OECl) and others, to help in articulating the vision of quality cancer care. This has notably included ongoing publications within the Essential Requirements for Quality Cancer Care44 series, with more recently completed consensus expressions being made available for ovarian45, glioma46 and pancreatic47 cancer. It also includes active support towards systems for quality assuring cancer care, such as the OECl accreditation and designation programme48.

A common theme of all such initiatives is the importance of achieving a shared understanding across borders of the key elements of quality cancer care, and in defining and then implementing strategies for their achievement.

Europe’s Beating Cancer Plan: drawing on considered conclusions

Europe’s Beating Cancer Plan did not start from an entirely blank page. Alongside a myriad of well-established European level initiatives and projects, such as those referenced above, a strong legacy of considerations and consensus on aspects of quality cancer care was also inherited from several previous EU “Joint Actions” on cancer. In addition to a Joint Action on Rare Cancers (JARC), a series of concurrent Joint Actions included the Innovative Partnership for Action Against Cancer (iPAAC) 2018–21, the European Guide on Quality Improvement in Comprehensive Cancer Control (CanCon) 2014–17, and the European Partnership for Action Against Cancer (EPAAC) 2008–13. At the same time, important investments and precedents for cross-border cooperation between cancer centres were also being developed via a range of European Reference Networks with focus on cancer. Taken together, they have built up a cross-border community of cooperation in cancer treatment, and also established an increasing shared understanding at a governmental level of the value of comprehensive cancer care models as a means to organise and deliver quality cancer for patients in any health system.

From such roots emerged one of the key legacy flagships of Europe’s Beating Cancer Plan in 2021: the commitment to achieving an EU Network of Comprehensive Cancer Centres, and a common goal of ensuring that 90% of eligible patients have access to such centres by 2030.

Through subsequent EU funding investments, such as the current Joint Actions CRANE, JANE and CCI4EU, alongside a range of European Reference Networks with cancer focus, landmark progress is underway towards these ambitions. Countries that did not previously have in place access to comprehensive cancer care centres and networks will now do so as a result of Europe’s Beating Cancer Plan. Many thousands of patients will benefit from improved cancer care provision as a result, a truly meaningful action in reducing inequalities in cancer care across countries. It is also hoped that such developments can, in time, further the quality of translational, clinical and outcomes research in all countries, and better integrate clinical care and research49.

Going all the way: enhancing the delivery of the comprehensive cancer care goal

Recommitting to the EU’s comprehensive cancer care access goal

The development of an EU Network of Comprehensive Cancer Centres is a strong area of future legacy for Europe’s Beating Cancer Plan:

- tackling directly known inequalities in cancer care by ensuring cancer patients in every EU country can access comprehensive cancer care
• providing a framework upon which many future cooperation initiatives can develop, including new forms of multidisciplinary research cooperation

The commitment to delivering an EU Network of Comprehensive Cancer Centres should be restated by the next European Commission, and the successes in improving cancer patient access celebrated and reinforced. This is especially the case for countries where comprehensive cancer centres did not exist prior to 2019.

**Twinning: the power of connection**

In order to support the achievement of the EU’s comprehensive cancer centre access target, twinning of cancer centres has been an approach supported by EU financial instruments. This helps to advance sharing of learning and approaches between well-established comprehensive cancer centres and those more recently established, or en route to be established.

However, it has been identified that the levels of financial support for twinning to date have been modest, and the duration of the financing period for the twinning programmes limited, in some cases to two years or less.

This inhibits the potential of twinning to support all countries in Europe in meeting raised standards of cancer care.

The next stages of implementation of the EU comprehensive cancer centre goal should give additional support to the cancer centre twinning concept.

**Expanding the benefit: for all**

The EU Network of Comprehensive Cancer Centres is a tangible and exciting ‘grand project’ which is already stimulating important improvements in patient access across Europe to high quality multidisciplinary cancer care in centres of verified expertise and standing.

It is also a principle of business management theory (Metcalfe’s Law) that the value of a network system grows at a square of the number of users.

Presently the EU Network of Comprehensive Cancer Centres welcomes participation from some countries outside of the EU, such as Norway. However, pathways for participation do not yet exist for cancer centres in countries such as the Western Balkan EU candidate countries, Ukraine, Moldova, as well as the United Kingdom, and Switzerland.

In much the same way that participation in the EU Horizon research programme is promoted to non-EU countries, emphasis should be given in the next European Commission period to permitting new countries to join the EU Network of Comprehensive Cancer Centres.

**Joining the dots: the EU Network of Comprehensive Cancer Centres at the heart of change**

Flagships of Europe’s Beating Cancer Plan and the EU Research Mission on Cancer should not be isolated silos. Each can reinforce the other. Connections should be promoted and supported.

In the case of the EU Network of Comprehensive Cancer Centres, connections that might be helpfully strengthened in future include:

• With the implementation of some recommendations of the UNCANEU project (to be published November 2023); and,
  • Mutual support of the new EU Networks of expertise on cancer and cancer conditions (Joint Action JANE).

In implementing the EU Network of Comprehensive Cancer Centres, recognition must also be made of the variety of high impact independent European endeavours led by scientific, healthcare professional and other societies. These should be able to ‘plug in’ to EU endeavours to improve quality of cancer care. Examples include centre certification and accreditation systems such as those operated by the OECI and German Cancer Aid.
5. Digital health: a powerful ally in the fight against cancer

Unlocking the potential of digital for cancer

Cancer systems in every country face the testing scenario of increasing incidence of cancer set against constrained and finite resources. Attention must necessarily be given to new sources of support to help achieve the vision of high-quality cancer care for all. Ongoing and rapid advances across many fields of digital healthcare are a signal of digital health’s growing promise to help. This includes, but is not limited to:

• The role of big data to drive new insights and discovery in all fields of cancer research, including in respect to prevention, detection, diagnosis, treatment and survivorship understanding;
• The contribution of artificial intelligence (AI) to bring new levels of precision and speed to processes, including diagnosis and clinical research;
• The patient convenience and efficiency-gaining opportunities provided by ongoing advances in telehealth and telemedicine, which can also support in tackling inequalities such as noted rural-urban inequalities in access to quality cancer care; and,
• The benefits of digitising medication management processes to support improved patient safety, better use of healthcare professional time, and reductions in bureaucratic procedure.

Not just a digital Europe; a digital health Europe.

The European Union is helping to sponsor digital transformation across member states through ambitious initiatives such as the “Digital Europe” programme. This is augmented by contributions from the EU4Health programme in respect to such needs as offering new training and education opportunities for health and oncology professionals, whose role is vital in helping to lead change in their hospitals and cancer centres.

Further to this, far-sighted legislative proposals from the European Commission promise to untap new opportunities in health and oncology data cooperation across borders, including via the forthcoming European Health Data Space. Concurrently the European Commission is supporting the environment for AI’s application in cancer care by helping to ensure an appropriate regulatory framework such as via the EU Artificial Intelligence Act.

However, in such a fast-moving field, there can be no room for self-congratulation. Honest conversations are also required about risks of over-regulation, as well as concerns about growing ‘digital divides’ both between and within countries. In this spirit, the following recommendations are presented.

Time to accelerate: for digital cancer care

The European Health Data Space – getting it right first time

The European Health Data Space (EHDS) represents an excellent prospective tool for improving the sharing and use of health data for both primary and secondary health purposes. For cancer patients, new opportunities for cross-border care can be achieved. In cancer research, new insights on topics such as cancer causation, early detection and long-term survivorship issues, could all be gained, if, the regulation underpinning the European Health Data Space is proportionate and well purposed:

• Trust in the European Health Data Space should be assured by the inclusion of patients and healthcare professionals in its governance board.
• The risk of disproportionate regulation should be avoided. Currently mooted concepts of requiring citizens to opt in to consent for their data to be used for secondary research purposes, even when used in pseudonymised form, are not supported. As currently being put forward, such requirements would compromise the Data Space’s promise through introduction of a range of data biases, and further burden healthcare professional time to operate a set of requirements that go beyond the already international gold standard consent requirements provided by the General Data Protection Regulation (GDPR).
• If an opt out mechanism is agreed as a political compromise, a full impact assessment of this approach should be foreseen by the Regulation, and any solution must be pragmatic and well aligned across all Member States. This is necessary to avoid the current heterogeneous approaches that are in being applied with respect to GDPR’s application to health research across the EU being replicated in a similar manner during implementation stages of the European Health Data Space.
• Implementation of the European Health Data Space should be accompanied by a well-resourced, targeted and calibrated support mechanism to help develop health data infrastructures across all EU countries, taking inspiration from the implementation approaches underpinning other EU goals such as the creation of an EU Network of Comprehensive Cancer Centres. Budget to deliver the EHDS should go beyond the Commission’s proposal with a focus on investment in public and non-profit infrastructure to support delivery of a well-functioning EHDS.
Artificial intelligence: a driver of improvement

- The application of artificial intelligence to many components of cancer care and research is a major opportunity area for the present and future. High quality digital systems to generate data for AI is a critical imperative in this respect. Ongoing actions by the EU to support these developments are requested, including via regulatory updates and through targeted research funding.
- The particular advances being made in the use of AI to assist cancer screening and detection services indicate a general need for readiness to be able to adapt EU level recommendations and guidance in the field based on practice results in the years ahead, and for all cancer policy makers to be highly alert to AI as a driver for change in cancer policy approaches. The expertise and insights of AI specialists will be increasingly important, as will meeting related oncology professional education needs connected to such technologies.
- Fundamental to advancing AI in cancer care is improving understanding of the technology among health system planners, cancer centre directors and professionals in practices. Current EU level investments to support this need should be maintained and enhanced and countries be encouraged to adopt knowledge management approaches to this end.

Opportunities left uncompleted: digitising medication management, registry interoperability, and telemedicine

- With the urgent need to make more efficient use of the time of every oncology professional, to safeguard patient safety and reduce bureaucracy, completing the task of full digitisation of all medication management systems should be taken as a shared European goal.
- Areas of unfulfilled potential in respect to European cancer registry interoperability should be commonly identified and addressed. Matters requiring further attention, as brought forward by stakeholders in developing this manifesto, include, capture of patient ethnicity data, cancer recurrence, cancer metastasis and cancer co-morbidity. Failure to address these information fields in registry systems leads to lost insights, poorer policy response to needs, and missed opportunity for cross-border cancer cooperation. Political targets and funding support should be brought forward to address Europe’s gaps on cancer registry interoperability.
- In too many parts of Europe, the promise of telemedicine is frustrated by outdated procedures and regulation. In many countries reimbursement models make telehealth and telemedicine not possible. Connected to the EU’s Digital Europe agenda, it is recommended that the European Commission’s Directorate General for Communications Networks, Content and Technology (DG CONNECT), help facilitate and support countries to overcome and remove such barriers.
6. All cancer patients equal: achieving that vision

1. Equal Access

You have a right to:

Equal access to affordable and optimal cancer care, including the right to a second opinion.

All cancer patients should have equal rights to quality cancer care as called for by the European Code of Cancer Practice. However, data and evidence on the topic delivers a sharp wake-up call on the need for action on Europe’s cancer inequalities.

Inequalities in cancer care are spread across different countries in Europe, and within countries, between regions, and across different segments of society, based on different social determinants of inequalities. Inequalities have been studied and defined across different socioeconomic status, different age categories, educational level and based on being part of different social groups.

Shining light on the problems: the European Cancer Pulse

The European Cancer Pulse is a data visualisation tool launched in November 2022. The Pulse includes data on national cancer inequalities across the WHO Europe region, covering the whole cancer continuum from prevention to survivorship and quality of life. The Pulse also provides data on social inequalities affecting cancer care, such as disparities based on age, gender, income, education, or being part of a marginalised community. The tool collects and makes available in one easily accessible portal a variety of data on cancer inequalities that would otherwise be scattered. In so doing, the Pulse also highlights gaps in knowledge still present on the topics. By providing easily accessible data to cancer policy opinion-formers and decision-makers, the Pulse aims at improving the basis for evidence-based policy interventions that can positively move the needle on tackling cancer inequalities across Europe. It is an allied initiative of National and European Parliamentarians for Cancer Action, and aims to provide a complement to the excellent European Cancer Inequalities Registry.

We encourage all readers to familiarise and explore the tool at europeancancer.org/pulse.

Breast cancer screening: disparities between and within countries

<table>
<thead>
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<th>Country</th>
<th>Indicator</th>
<th>Value</th>
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<th>Source</th>
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<td>Very high income</td>
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Europe’s Beating Cancer Plan: a new landmark in political recognition of Europe’s cancer inequalities

When Europe’s eagerly awaited Beating Cancer Plan was published in February 2021, it was a welcome development for the cancer community to find not only a chapter dedicated to the combat of cancer inequalities, but also the commitment to a brand new cross-border monitoring tool on the topic, the European Cancer Inequalities Registry. Subsequently developed with experts at the European Commission’s Joint Research Centre, the Organisation for Economic Co-operation and Development (OECD), and the International Agency for Research on Cancer (IARC), the registry is providing fresh insights into Europe’s cancer inequalities and challenges. It is stimulating new thinking about national and pan-national level responses.

For example, the OECD’s “EU Country Cancer Profiles”\textsuperscript{54}, published in February 2023, synthesise data on national cancer burden, risk factors for cancer, implementation of early detection programs, and performance of cancer care. They identify strengths, challenges and other areas of action in order to guide interventions. The Joint Research Centre’s ECIR data tools\textsuperscript{55}, allow members of the public, researchers and many others, to generate a range of visual insights into areas of cancer inequalities such as by cancer site, by social determinant, and cancer stage. Future work by the International Agency for Research on Cancer (IARC), will add to our understanding and response to social inequalities in cancer.

However, such exercises, by their very nature, also inevitably reveal some of the sharp gaps that exist in readily comparable, but highly relevant and necessary data when it comes to cancer inequalities. This includes, but is not limited to, such matters as:

- inequalities related to ethnicity, and,
- patient access to key forms of care and treatment, such as the availability of relevant cancer specialist services, with a non-exhaustive list of examples including pathology, radiology services, nuclear medicine, oncology pharmacy, cancer nursing, oncology surgery, radiation oncology, medical oncology, palliative care, clinical nutrition, psycho-oncology support and many other elements, such as rehabilitation and social support services, that form the basis of any patient’s experience (or not) of quality cancer care. This also includes access levels to clinical trials.

Turbo-charging the fight against cancer inequalities: the next steps together

Addressing data gaps

The establishment of the European Cancer Inequalities Registry is applauded as a ground-breaking policy tracking tool for cancer at the EU level. For next stages of development, the cancer community recommends:

- Concerted efforts with relevant agencies such as EUROSTAT and others, including civil society, to ensure better coverage to important areas of cancer inequalities such as patient access to key services and professions, especially in view of a current health workforce shortage crisis.
- Recognition that indicators should be included to better understand inequalities in cancer related to specific segments of society. This includes, but is not limited to: older persons, adolescents and young adults, racialised communities, Roma, undocumented migrants, refugees from areas of conflict, individuals from the LGBTQI+ community, persons in institutionalised settings, neuro-divergent individuals, and persons with physical disabilities.

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**Education: proportion of daily smokers of cigarettes per education level**

<table>
<thead>
<tr>
<th>Country</th>
<th>Indicator</th>
<th>Value</th>
<th>Year</th>
<th>Source</th>
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<td>2019</td>
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</tr>
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<td>Hungary</td>
<td>Proportion of daily smokers of cigarettes</td>
<td>Primary education: 25.30%</td>
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<td>Eurostat</td>
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<td>Hungary</td>
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<tr>
<td>Hungary</td>
<td>Proportion of daily smokers of cigarettes</td>
<td>Tertiary education 8.60%</td>
<td>2019</td>
<td>Eurostat</td>
</tr>
</tbody>
</table>
Acting on the data

The European Cancer Inequalities Registry should be the foundation of evidence-based cancer policy intervention at the EU level:

- Informing implementation strategies for key elements of Europe’s Beating and Research Mission on Cancer (e.g. creating a tobacco free generation, eliminating HPV cancers).
- Being a basis for decision-making in respect to major EU health funding programmes such as EU4Health and the Horizon Europe research programme. This could include investment in improving standardised EU wide inequalities data collection e.g. through the European Network of Cancer Registries (ENCR).

Data from the European Cancer Inequalities Registry should be used to form an annual EU-level report on the status of Europe’s fight against cancer inequalities, with accompanying recommendations to EU Member States, similar in nature to (and allied with) the EU Semester process. The report should be the basis of an annual European governmental level conference on cancer inequalities.

Geographic divides

Flagship initiatives, and other components, of Europe’s Beating Cancer Plan and EU Research Mission on Cancer, should all have strong orientation towards addressing geographic cancer inequalities in Europe. This includes, for example, the EU Network of Comprehensive Cancer Centres, and goals such as tobacco free generation and HPV cancer elimination. Funding towards these goals should be targeted accordingly, with areas of Europe most in need of support receiving priority.

An assessment should be conducted into the operation of EU health and research related funding programmes to ensure their optimal accessibility for countries and regions of Europe with lower than EU average Gross National Income.

The EU’s landmark cooperation in cancer policy should be open for participation and collaboration with non-EU countries, including EU candidate and accession countries such as Ukraine, Moldova, and Western Balkan countries.

The EU should further develop its leadership role in cancer policy at the international level, being a key and active partner in supporting the achievement of WHO goals such as cervical cancer elimination in all countries.

Urban-rural disparities in cancer care

As part of the European Cancer Inequalities Registry exercise, an EU funded project should be conducted to better understand the nature and extent of rural-urban cancer inequalities across Europe and the best practices for addressing these.

The work programmes of the EU’s Horizon Europe, EU4Health and Digital Europe programmes should be encouraged to include projects that can support the deployment of new approaches to tackling the challenges of cancer care provision in rural areas, including: less access by patients to the oncology workforce; travel distances to services^56; and barriers to clinical trial access.

Outer regions of the EU^57

As part of the evaluation of Europe’s Beating Cancer Plan and the EU Research Mission on Cancer, attention should be provided to understanding the engagement so far of outer regions of the EU such as the Azores, the Canary Islands and Ultra-marine regions.

Social inequalities: age

Older persons: In the context of Europe’s good news story of longer life expectancy, and with cancer as an age-related condition, it is important that:

- Health systems treat older cancer patients with dignity, with clinical decisions made not on the basis of age alone, but on the patient’s unique circumstances
- The uptake of tools, such as geriatric screening, geriatric oncology education, and specialised patient navigation tools, should be promoted at EU level, with access to such services monitored as part of the European Cancer Inequalities Registry
- There is continual improvement of the European clinical trial landscape, including stronger inclusion of older persons in trials, and improved understanding of cancer co-morbidities
Adolescents and young adults: The particularities of cancer inequalities, as experienced by younger cancer patients, should be recognised and responded to, including through the achievement of a universal legal ‘right to be forgotten’ across Europe and improved access to fertility counselling and preservation and support on assisted conceiving.

Gender

Gender related inequalities in cancer policy should be recognised and responded to in the further implementation of Europe’s Beating Cancer Plan and EU Research Mission on Cancer. This includes, but is not limited to:

• Achieving gender neutral HPV vaccination policies in all countries.
• Delivering the promise of new EU Council Recommendations for Cancer Screening, including for breast, cervical and prostate cancer.
• Responding to data on gender related cancer inequalities, in fields such as prevention and clinical trial participation, with more targeted and gender sensitive policy responses.
• Ensuring that all gender inequalities are addressed and that work in this area is not viewed as being a binary choice between men and women.

LGBTQI+

• Greater recognition, and further research, to reflect the specificities of cancer policy connected to gender non-conforming individuals, such as for cancer screening.
• As part of the EU’s aim of achieving a ‘a Union of Equality’ by 2025, all health and cancer care systems should be provided with encouragement and shared tools to help achieve safe, inclusive and positive environments within health and cancer care systems for patients and professionals from the LGBTQI+ community.

Ethnicity

• To address a major gap in current European oncology data and research, all cancer registries in Europe should be encouraged to improve their collection of data on patient ethnicity.
• Anti-racism and anti-discrimination policies and practices within health and cancer care systems should be strengthened, including in respect to workforce recruitment and retainment.

Overall recommendations

• Europe’s cancer care systems, and its oncology workforce, should be supported in having increased understanding and sensitivity to social inequalities in cancer care. This could include provision in training and education in relevant areas, such as unconscious bias and the use of appropriate and inclusive language, and be developed for healthcare professionals in primary, secondary and tertiary care.
• Barriers to access to health, cancer care and clinical trials associated to historically marginalised communities should be recognised and responded to in both EU and national level cancer policy. Among the responses to be considered are targeted health literacy programmes for marginalised and minority populations.
• In forming and implementing cancer policy, proactive efforts should be made to ensure consultation and input from all marginalised communities, including, but not limited to: older persons, adolescents and young adults, racialised communities, Roma, undocumented migrants, individuals from the LGBTQI+ community, persons in institutionalised settings, neuro-divergent individuals, and persons with physical and/or learning disabilities.
Every year 3.5 million people in Europe will receive a cancer diagnosis and begin a new journey of treatment and care. Further to this, it is estimated that there are now over 20 million citizens living after a cancer diagnosis. A population demographic larger than Romania, the EU’s sixth largest country. This latter fact is good news reflecting growing success in detecting and treating many (but not all) cancer types. However, such figures cannot hide the individual and daily endurances that so many cancer survivors and their care-givers must face on a daily basis, often without need, if only more supporting policy environments were in place.

Europe’s cancer survivors frequently struggle from physical, psychological, economic and social impacts arising from their diagnosis, treatment, as well as in later life “after cancer”. Among just some of the physical long-term impacts from a cancer diagnosis and treatment are chronic pain, fatigue, cognitive impairment, loss of body strength, sexual dysfunction, incontinence, mobility impairment, hearing loss, cardiomyopathy, and speech impairment. Psychological impacts can include but are not limited to: anxiety; distress; depression; suicidal thoughts; body image disturbance, and more. Compounding this, lack of legal protections can add greatly to the suffering associated with cancer, including lost income, high out of pocket expenses and a failure to protect cancer patients and survivors from discrimination in such fields as access to financial services (mortgages, loans, insurance) and the right to return to work. Europe’s fight against cancer must provide attention and compassion to Europe’s cancer survivors, their families and care-givers. Opportunities to gain improvement abound if the political will for their delivery can be summoned.

Solid foundations: Europe coming together on survivorship and quality of life

Europe’s Beating Cancer Plan, in combination with the EU Research Mission on Cancer, has set out some impressive new directions for a shared EU response to its Member States need for stronger cancer survivorship and quality of life policy. This includes, but is not limited to:
• The smartCARE project – to develop a cancer survivor smart card – in the form of a mobile app – to improve the health and wellbeing of cancer survivors throughout Europe;
• EU–CAYAS–NET – to improve the quality of life of childhood, adolescent and young adult cancer survivors through improved social networking and the use of a platform to improve the links amongst individuals, patients, cancer survivors, and social and health professionals active in cancer prevention and care across the Union.
• The EUonQoL project – to create a European Oncology Quality of Life Toolkit (EUonQoL-kit), a patient-centred unified tool for the assessment of quality of life among cancer patients and survivors
• Many Horizon Research projects to support increased understanding across Europe of the treatment and policy interventions that can make the greatest impact for cancer survivorship and quality of life. These include, but are not limited to,
  • The 4D PICTURE project to redesign care paths for patients with breast cancer, prostate cancer and melanoma.
  • The EU–Navigate project to create a navigation intervention for older people with cancer and their family caregivers in different health care systems in Europe.
  • The MyPath project to develop electronic patient-centred care pathways – custom-made for each individual patient, including real-time communication of symptoms and care preferences.

Further to this, Europe’s Beating Cancer Plan has also committed to the conduct of studies in respect to where the EU may be able to facilitate greater protections for cancer patients and survivors returning to work or education, and protections against discrimination by financial service providers. However, in these cases, concerns exist that voluntary approaches to the protection of core citizen rights will leave too survivors unprotected, where a strong case for legislative response exists.

As we look to a future of both increasing cancer incidence, and cancer survivorship, there can be no relaxation of the momentum for well-formed and targeted cancer survivorship and quality of life policy. Recommendations follow.

Building on foundations: identified opportunities for enhanced survivorship and quality of life policy. An EU–wide legal right to be forgotten for cancer survivors

An increasing number of European countries are making substantial progress towards recognising new legal rights for cancer survivors, with notable leaders in this effort being Belgium, France, the Netherlands, Portugal, Romania, and Spain. While these six countries have already enacted national
provisions, several other countries, including Cyprus, Italy, Malta and Slovenia, are actively working to implement similar measures.

This momentum shows no signs of slowing down, as every EU country is now set to establish the right to be forgotten for cancer survivors, following the adoption of the Consumer Credit Directive, mandating Member States to incorporate provisions on this right by 2025. In the next two years, we can anticipate a wave of legislative changes to meet this obligation.

Notably, some countries have already taken proactive steps by implementing codes of conduct or self-regulatory policies that offer choices and protections to individuals with a cancer history. Luxembourg, Denmark, Finland, Greece and Ireland are among those leading the way in this regard.

**A European Cancer Survivorship Day**

To help all countries recognise and respond to the policy challenges involved, the European Union is encouraged to establish a European Cancer Survivorship Day. Connecting with other similar international initiatives, purposes would include:

- heightening awareness to the challenges of cancer survivorship;
- drawing attention to inequalities in cancer survivorship;
- providing a platform for the many important EU supported initiatives in cancer survivorship and quality of life; and,
- marking and celebrating successes, and the quality lives being lived due to progress in the fight against cancer.

**Improving the collection, analysis and response to survivorship data**

Recommended areas for the European Cancer Inequalities Registry and Eurostat to improve data collection include: patient access to key professional services such as palliative care, nutritional support, psycho-oncology, supportive care, physiotherapy and rehabilitation services, sexual medicine, and pain medicine; and the extent and quality of survivorship care planning.

**Ongoing support for flagship EU projects now underway to support cancer survivors**

Europe’s Beating Cancer Plan and the EU Research Mission on Cancer have initiated a number of highly promising projects to deliver better support for cancer survivors. These include, but are not limited to, smartCARE, the EU Network of Youth Cancer Survivors (EU-CAYAS-NET), EUonQOL, STRONG-AYA, the EU Carers Strategy, and many others.

All will require sustained EU funding and strengthened linkage at national level to reach their fullest potential.

**European standards and guidelines for the delivery of survivorship care planning**

Europe’s Beating Cancer Plan and the EU Research Mission on Cancer is creating a variety of new foundations for European cooperation in the pursuit of high-quality cancer care, including for cancer survivors.

Opportunities should be pursued, in the context of goals such as creating an EU Network of Comprehensive Cancer Centres, or implementing pan-European Quality of Life indicators, to create and apply pan European standards and guidelines for survivorship care planning.

**Ensure new EU pharmaceutical legislation responds to the needs of Europe’s 20 million cancer survivors**

Health and cancer care is riven with a very large list of unmet medical needs. In the cancer sector this includes many cancer types of poor prognosis, such as lung, pancreatic, ovarian and glioma cancers. Unmet needs also include the many high impact symptoms of cancer, side effects and complications of treatment, and a large number of other quality of life impacts associated to a cancer diagnosis beyond survival prognosis.

For these reasons, ECO recommends a balanced approach that encourages treatment and development research for both areas of ‘high unmet medical need’ relating to indicators such as survival rate, but also ensures research and development be encouraged to address other forms of unmet medical need. Other unmet medical needs in respect of cancer survivors includes achieving reduced side effects of treatment such as acute and late toxicity and other side effects such as nausea, cognitive impairment and dysfunction, fatigue, pain and cachexia, as well endocrine, cardiac, metabolic and fertility issues.
Rehabilitation, including reintegration into the workplace

Following a 2023 WHO resolution on rehabilitation\textsuperscript{63}, the EU, via the Directorate-General for Employment, Social Affairs and Inclusion (DG EMPL) and the Directorate-General for Health and Food Safety (DG SANTE), should actively support the creation of new targets and indicators to advance rehabilitation in health systems.

DG SANTE and DG EMPL should cooperate in conducting joint studies into:

- Levels of workplace and education discrimination and employer facilitation in respect to cancer patients undergoing treatment or returning to work or education; and,
- The socio-economic benefits of governmental investment in rehabilitation services

The mandate of, and instructions to, the European Agency for Safety and Health at Work (EU-OSHA), to be active in respect to Return to Work policy, should be refreshed and expanded, including in producing official guidance to employers and countries.

Fertility preservation

In 2022 a full plenary vote of the European Parliament passed consensus recommendations (via the BECA report\textsuperscript{64}) that EU level guidelines should be developed to deliver a shared understanding across countries about the timing and way cancer patients should be informed about the availability of reproductive options. The request of the Parliament should be honoured.

All EU Member States should be encouraged to make provision of reproductive procedures for cancer patients reimbursable as part of universal healthcare coverage.

Cancer co-morbidities and complications

Efforts should be made to improve the understanding and policy response to cancer co-morbidities and complications. This should include:

- Encouraging all cancer registries to capture and report comorbidities and complications from cancer treatment.
- Bringing about a powerful European Health Dataspace that enables secondary health research to take place with large cross border datasets, unhindered by excessive regulatory burden.
8. An oncology workforce in crisis: they care for us, do we care for them?

The oncology workforce shortage: it is not a timebomb. It is already here.

Europe’s cancer professionals are the engines that drive the performance of healthcare systems to combat cancer and achieve better outcomes. There can be no cancer prevention, diagnosis, treatment, care, follow-up and survivorship care without a cancer workforce. Indeed, as expressed by the European Code of Cancer Practice, every cancer patient should expect, as a right, to receive care from a specialised multidisciplinary team (Right Number 4).

Yet, the right of cancer patients to specialised multidisciplinary cancer care can never be achieved while the acute and pressing crisis in oncology workforce shortage are left unaddressed.

WORKFORCE SHORTAGE AS A FURTHER DRIVER OF INEQUALITY IN CANCER CARE

Precise and comparable data across EU countries, according to specialties, is not presently publicly collected and published as a common resource to aid policy making and cross border health workforce planning. However, such information as there is, presents an impression too, of the inequity in availability of professional care and treatment across Europe.

<table>
<thead>
<tr>
<th>Country</th>
<th>Indicator</th>
<th>Value</th>
<th>Year</th>
<th>Source</th>
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<td>2019</td>
<td>EUROSTAT</td>
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<td>2020</td>
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<td></td>
<td>20.27</td>
<td>2021</td>
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</tbody>
</table>

Oncology workforce shortages lead to a wide range of harmful impacts including:

• Delays in detection, accurate diagnosis and start of patient treatment;
• Less time for clinical care between professional and patient, impacting clinical decision-making and the quality of care received by the patient;
• Heightened probability of patient safety incidents occurring in a treatment area involving high risk medicines and procedures;
• Symptoms of burnout, depression and other negative impacts on the health and wellbeing of over-worked professionals operating in understaffed environments; and,
• Dissatisfied professionals leaving the oncology and health sector permanently, further compounding the workforce shortage.

“The health workforce crisis in Europe is no longer a looming threat – it is here and now.”

Dr Hans Henri P. Kluge, WHO Regional Director for Europe, March 2023

Going beyond projects: the case for an EU Action Plan on addressing health workforce shortages.

It took the COVID-19 pandemic to awaken political attention to the pre-existing vulnerabilities that all health systems face in respect to matters such as medicine shortage and medical product shortage. Admirable lesson learning has occurred as evidenced by the rapid response to more fully empower relevant actors such as the European Medicines Agency and new EU Health Emergency Preparedness and Response department to be active and involved in preventing such shortages, and better managing cross-border cooperation when they do occur. Sadly, no such lesson has been learnt yet in respect to addressing health workforce shortage, another salient feature of the COVID-19 pandemic. This must change before the impacts of chronic staff shortage become compounded, respecting that any solutions will take time to deliver their impact.
Time to accelerate: for Europe’s oncology professionals.

To address Europe’s health and oncology workforce crisis, the following actions are recommended:

- To remedy the problem at the highest level, **EU Council Recommendations on addressing Europe’s health workforce crisis** should be developed and agreed by all 27 EU Member State Governments. Such Recommendations should be achieved via a co-creation process involving wide, public and targeted stakeholder consultation.

- Allied to these **Council Recommendation, an EU level study** into the extent, causes and policy solutions to health workforce shortage should be immediately commissioned. Issues covered should include: impacts to patient care, wellbeing impacts for healthcare professionals, the opportunities for reductions in bureaucracy to play a role in addressing the crisis, and the role of task-sharing and digital solutions to support efficient use of health and oncology professional time. The study should also examine the immediate term, mid-term and long-term skills needs and gaps in oncology care across Europe, and the role of primary care to better support best use of resource in health and oncology care.

- **Eurostat** should be provided with mandate and budget to conduct thorough exercises in reporting health workforce resource capacity across the EU.

- Reporting on inequalities in patient access to key oncology professions as part of **the European Cancer Inequalities Registry**. This should ideally include indicators on not only workforce number but also indicators of workforce wellbeing.

- The **EU Health Emergency Preparedness and Response department** should also be given remit to conduct health workforce mapping and planning roles.

- Elements of the EU’s new **Mental Health Action Plan** should be targeted towards the support of healthcare professional mental wellbeing needs.

- **The role of the EU’s Digital Europe and EU4Health programme** in driving better use of digital technology in healthcare should be reinforced with the need for action to address the health workforce crisis in mind and include focus on supporting the achievement of fully digitised healthcare delivery in all countries, including digitised medication management.
9. An agenda whose time has come: health systems and treatment optimisation

In a world of finite resource and in a setting where outcomes are vital, in the truest sense of that word, a continuing vigilance and response is needed to ensure our systems for cancer care and research are fit for purpose. It is to these needs that the health and treatment optimisation agenda responds.

As stated in resolutions passed at the European Cancer Summit 2020:

“Research in cancer care should address questions relevant and meaningful for patients and public health. Such research should follow an independent process to support optimal access for patients to evidence-based multidisciplinary cancer treatment.

To achieve this, a reorientation of health systems and research approaches in cancer is needed. This requires addressing gaps in clinical and health services research applied to cancer through a reverse engineering approach, starting with better definition of the important clinical and public health questions.”

While such goals find support across stakeholder communities, including the member societies of the European Cancer Organisation, and its Patient Advisory Committee, a full-hearted response to bring about such reorientation remains lacking. However, elements of more recent progress include:

• Emerging newer approaches in research such as the advent of growing numbers of ‘pragmatic clinical trials’;
• The establishment by the European Medicines Agency of a ‘Cancer Medicines Forum’ bringing together representatives from academic organisations and the European medicines regulatory network, with the aim of advancing research into optimising cancer treatments;
• At an international level, and promoted by growing numbers of governments, a specific WHO agenda on strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination.

Despite all of this, much more might yet be committed towards the pressing need for health systems and treatment optimisation.

Time to accelerate: health systems and treatment optimisation

A formal embrace of the health systems and treatment optimisation agenda

In a context of growing demand upon all countries’ health systems, and finite public resources, the time is overdue for a comprehensive political uptake of the health systems and treatment optimisation agenda.

To support this agenda, we urge EU Council Recommendations on Health Systems and Treatment Optimisation, including:

• Defined aims and actions that European countries are willing to commit to together towards this goal
• Confirming inter-governmental support to emerging opportunities such as the pragmatic clinical trial agenda, led by academic research organisations such as the EORTC
• Promoting further inclusion of pragmatic trial calls within research programmes such as Horizon
• Instruction for the orientation of, and attention within, EU funding streams towards optimisation needs including Horizon Europe and EU4Health
• Attention and response to the infrastructural needs supporting health systems and treatment optimisation, including trials, data and regulations.

Consideration of the opportunities available within present EU initiatives to produce progress

Those with roles in the creation and delivery of key areas of EU cancer and health policy should be mindful of opportunities to give support to the health systems and treatment optimisation agenda. This includes, but is not limited to:

• The operation of relevant regulatory agencies and fora, such as the European Medicines Agency (EMA) and the Heads of Medicines Agency (HMA), with the operation of a new EMA Cancer Medicines Forum being a good example in this respect.
• The creation of new structures and processes for Health Technology Assessment (HTA) cooperation in Europe, such as the ongoing implementation of the new EU HTA regulation.
• The development of novel tools supporting health data cooperation across borders for research purposes, including the European Health Data Space.
EU leadership at an international level to advance the health systems and treatment optimisation agenda

The EU and its Member States should engage proactively in cooperation initiatives to more optimally translate available clinical evidence into the health system, to support health system sustainability and resilience. Such identified areas of opportunity for international cooperation on health systems and treatment optimisation include, but are not limited to:

- Present World Health Organization efforts to strengthen clinical trials and improve research quality and cooperation; and,
- Forums for international regulatory and clinical research cooperation, with examples including the International Association of Medical Regulatory Authorities.
10. In crisis we need cooperation the most

Cancer care in an era of permacrisis

We now live an era of ‘poly-crisis’, or even ‘permacrisis’. The likelihood of future pandemics is said to be increased by ongoing advances in globalisation and connectivity. War has returned to Europe, a spectre that was previously hoped to have been banished. Climate related environmental disasters are recorded to be increasing, including heatwaves, flooding and forest fires. Natural disasters, such as earthquakes impacting urbanised areas, remain a real and present reality in Europe. Public resources for health and cancer care are stretched in almost every country. Antimicrobial resistance continues to haunt healthcare provision, with its particular impacts for cancer including the vulnerability of people with immunosuppression. Each alone can significantly disrupt cancer care. In too many cases, it is now in substantial combination.

In the case of COVID-19, impacts recorded by the European Cancer Organisation during the pandemic included:
- Clinicians across Europe seeing 1.5 million fewer cancer patients in the first year of the pandemic;
- Urgent cancer referrals cut by up to half due to the pandemic;
- An estimated 100 million cancer screening tests not performed in Europe because of the pandemic; and,
- One million cancer patients not receiving a diagnosis, due to the backlog of screening tests, reduction and delays in referrals and restricted healthcare resources due to COVID-19.

No sooner was Europe and the world beginning to put the endurance of the COVID-19 pandemic behind it, than a fresh crisis was inflicted by Russia’s military invasion of Ukraine in February 2022. For the citizens of Ukraine, every aspect of life has been impacted as a result of this aggression, with cancer care no exception:
- More than 700 attacks on hospitals, health workers, and other medical infrastructure in Ukraine were reported in the first year since the Russian invasion began.
- With more than eight million persons in Ukraine calculated to have been internally displaced and more than six million refugee movements from Ukraine, sudden new needs were raised in assisting Ukrainian cancer patients with disrupted lives.

At the time of writing, additional conflict has arisen in Israel and Gaza, in a year that has also seen war in Nagorno-Karabakh, and intense destruction in Turkey and Syria as a result of earthquake. In all of these situations of human tragedy will be found cancer patients, cancer centres and oncology professionals, caught in the crisis with all others. In crisis we need cooperation the most.

In crisis comes opportunity for rapid learning and improvement

However, the COVID-19 pandemic and Russia’s military invasion of Ukraine, have both demonstrated political will and practical results, when countries work together to support each other’s needs, including the maintenance of cancer services to patients during crisis. The strength of civil society has also been expressed, especially so in the case of the rapid responses of Europe’s patient community to support cancer patients in need in Ukraine. The emergence of new infrastructures for cooperation, such as the Health Emergency Preparedness and Response Authority (HERA) are to be welcomed, and proposals currently being debated to strengthen the role and functions of the World Health Organisation in response to the pandemic are generally welcomed. Regulatory amendments to improve the role of the European Medicines Agency in such matters as the management of cross-border medicine shortages are positive and were long called for.

Sadly, it is also the case that not every lesson from recent crises in Europe have been learnt. Outside of amendments to the functions of the European Medicines Agency, more work remains to be completed to safeguard countries fully from ongoing chronic medicine shortages. Such shortages are often for essential cancer medicines. Medicines shortage threaten treatment outcomes, and create distress and negative health impact for patients. Furthermore, significant health resource, including pharmacy time, is lost to resolving shortages when they occur. Upstream causations of medicine shortages require further investigation and response, including production incentive problems in the generic medicine sector, and the best means for achieving re-shoring of medicines production to Europe.

It was a disappointment to the European Cancer Organisation not to see the Health Emergency Preparedness and Response Authority (HERA) equipped with a mandate to help countries address shared shortages in key health and oncology personnel. Health and oncology workforce shortage was a chronic problem in health systems prior to the COVID-19 pandemic, but its reality and impact were cruelly revealed at the height of the crisis.
Time to accelerate resilience and preparedness in European cancer care

Extracting every lesson from the COVID-19 pandemic

• A critical (yet seemingly yet unlearned) lesson from the COVID-19 pandemic is that Europe’s cross border crisis in health and oncology workforce shortage should no longer be left unaddressed. Building on the precedent of recent EU action on medicine and product shortage, a fresh and distinct European political agenda on health workforce resilience should be developed and implemented under the next European Commission 2024-29 (see Workforce section of the manifesto for further detail)
• Under a shared European political agenda, ongoing initiative should take place to achieve re-shoring of medicine production to Europe;
• The Health Emergency Preparedness and Response Authority (HERA) should develop into a distinct EU agency, akin to the European Medicines Agency (EMA) and European Centre for Disease Prevention and Control (ECDC), with its own distinct legal mandate, oversight structures and stakeholder engagement mechanisms (including Board level participation of healthcare professionals, patients, patient advocates and caregivers)
• The European Union should be an active and positive partner in supporting the achievement of a new international pandemic treaty, including facilitating Member States to reach common positioning, and, in so doing, bringing in relevant inputs and experiences from the handling of the COVID-19 pandemic from the European health and cancer community.
• The European Centre for Disease Prevention and Control (ECDC) should be given budget and mandate to build upon the success of the COVID-19 vaccine tracking facility by extending this powerful monitoring tool towards other vaccines, including HPV and Hepatitis B vaccination.

Supporting Ukraine now and in the future

• European Union and individual EU Member State financial support to Ukraine should be sustained, with clear understanding that funding purposeed for reconstruction must include application to cancer care services and infrastructure;
• Momentum to support the accession of Ukraine (and other countries) to full membership of the EU, with distinct packages of assistance to achieve further alignments with respect to such areas as EU regulations in the fields of professional qualification recognition, medicines regulation and clinical trial regulation;
• Recent explicit onus and incentivisation for Ukrainian inclusion with EU funded health and other projects should be maintained, with targeted guidance activity to help support new institutions and organisations from Ukraine to participate in EU projects for the first time.
11. Regulation as a tool for enabling better cancer care, not a barrier

The EU’s inescapable role in cancer care: legislation and regulation

Well before Europe’s Beating Cancer Plan and the EU Research Mission on Cancer, the European Union was always playing important, and inescapable, roles in cancer care, not least from the vital role it plays through development and implementation of standard-setting and public-interest-assuring regulation.

In a seemingly ever faster changing world, the task for EU regulation to keep up, let alone get ahead, appears as daunting as ever. Most of the time one might say EU regulation hits its target. However, sometimes, and often as a corollary of the compromise nature by which EU legislation must be finalised, negative impacts of regulation can be observed, and occasionally this also has consequence for those involved in delivering cancer care. Such effects are somewhat the nature of legislative process: fixing one problem but occasionally creating a new one through the law of unintended consequence. Frustration among stakeholders can mount however, when known problems with legislation appear unaddressed or even ignored. To Accelerate: Together Against Cancer provides the opportunity to summarise to the decision-makers in the next European Commission period 2024–2029, some of the fixes required to existing EU legislation. Some cautions are also expressed in respect to presently developing regulation, such as the European Commission’s proposed reforms to EU pharmaceutical legislation, currently subject to European Parliament scrutiny at the time of writing.

Fixing the fixable: taking action

The General Data Protection Regulation (GDPR) has provided a basis for Europe to be a global leader in the protection of personal data. Alongside the EU Data Governance Act, it can help to provide a basis for greater trust to develop in respect to altruistic donation of personal data for health and oncology research purposes. However, there remains ongoing complaint in respect to high divergence in interpretation of the regulation requirements across member states, which may in turn provide obstacle to cross-border trial cooperation.

It is recommended that, as part of the evaluation of the impact and implementation of GDPR, the European Commission conducts a study to examine the degree to which GDPR may have impacted cancer research in Europe since coming into force. The study should present concluding recommendations, including to Member State governments, on improving opportunities in respect to GDPR implementation, including facilitation of secure data exchange outside the EU or European Economic Area (EEA) for public health and academic research purposes.

In a similar vein, 2017’s new EU Medical Device Regulation, has experienced pains in its implementation, with many seeking to bring new devices into use in oncology and healthcare, reporting significant delay and blockage in the processes for CE-mark certification and re-certification71. The situation becomes more acute with a looming deadline of an estimated 23,700 certificates expiring in 2024. Pragmatic solutions to this overload of the notified bodies able to award such certificates are required, with the European Commission requested to play a facilitating role in their prompt achievement.

The European Union has significant and admirable aims in the field of personalised medicine, well captured by the still referenceable 2015 EU Council conclusions on personalised medicine72. This represented a shared consensus by EU Member States to work together in bringing forward the use of -omics technologies to deliver heightened effectiveness in therapeutic strategies for patients. In cancer care, this can be already commonly seen in the growing availability of genomic tumour testing. However, it is a great pity to report that in some cases, EU legislation, namely the 2017 In Vitro Diagnostics Regulation (IVDR), is now threatening patient access to such treatment therapies as difficulties in the regulation’s implementation impede access to genomic tumour testing, which relies strongly on in vitro diagnostics. Delays to the conduct of clinical trials in this field, as a consequence of IVDR, are reported to be between six and twelve months, and with little current sign of redress in the near future, over the coming years, many thousands of patients’ access to trials and treatment will be impacted. Implementation challenges have also been raised in respect to IVDR and the level of regulatory burden being placed upon academic laboratories producing in-house precision diagnostics. Taken together, without attention, IVDR risks creating inherent obstacles to the EU’s personalised medicine agenda73. Similar to the medical device regulation, searches for remedy to these implementation problems should be urgent, pragmatic and be led from the highest level within the European Commission.

An early achievement of the 2021–2024 European Commission was the eventual successful passage of new regulation to achieve greater and legally systematic cooperation in the area of health technology assessment – the 2021 ‘HTA regulation’74. With cancer medicines in the forefront of its early implementation, stakeholders are observing with interest the nascent construction of structures and processes for a mandatory ‘Joint Clinical Assessment’ of newly approved treatments. Mindful of matters that have developed with other regulations, every onus should be given to, as far as possible, to make things work
first time with the HTA regulation. Critical to this, and in the building of the widest trust and support in the
regulation, is the fullest and positive engagement of stakeholders. Clinical and patient experts need to be
actively engaged in the joint assessment processes. This can ensure that that the Joint Clinical Assessments
are of the best possible quality and optimally focused on clinical and patient needs. Furthermore,
structural involvement of medical societies and patient organizations is required in the development of
methodologies and guidelines as well as for the selection and training of experts. Thereafter, patients,
patient advocates and healthcare professionals should be deeply embedded within the ongoing strategic
decision-making about the implementation mechanisms of the regulation via meaningful processes. We
urge the model of the European Medicines Agency be looked to, in which high standards of transparency
are upheld and seats at the decision-making table are provided to stakeholders.

A key delivery tool of Europe’s Beating Cancer Plan is the EU4Health funding programme. With a €5.3
billion budget during the 2021–27 period, the funding programme powers many key promises of Europe’s
Beating Cancer Planincluding the creation of an EU Network of Comprehensive Cancer Centres, the rollout
of an inter-specialty cancer training programme to 100 cancer centres across Europe, the establishment
of an EU cancer survivor smartcard App, and projects supporting the EU goal of eliminating HPV caused
cancers. However, a significant Achilles heel to the operation of the programme is brought about legal
requirements that the programme be a co-funding programme. This means that in practice, for every
EU4Health funded project awarded, in normal circumstances, those awarded such a project, should
meet 40% of its costs, with 60% met by the EU4Health programme. With many key projects going over
10m EUR in scale, the many millions in missing funding for the recipient to secure is making application
impossible from many worthy and otherwise ready entities, often in countries impacted more severely
by cancer inequality. This anachronism, from a previous era when EU health funding programmes
was aiming to support conferences, has to be brought to an end. Legislation can be changed. The
EU4Health programme should no longer be a co-funding programme, but a fully funding programme.
It undermines its present purpose to be anything otherwise.

In 2015 the EU Professional Qualifications Directive completed an overhaul and modernisation. Great
ambitions were set. Administration procedures were promised to be simplified. Barriers to professional
mobility were to be reduced. Yet almost ten years later this is not the reported experience of many
European level professional societies, continuing to find no clear pathways through the legislation to
establish European level and legally recognised oncology specialty qualifications. In the context of
Europe’s health workforce crisis, and the experience of the COVID–19 pandemic, it appears perverse
that doors are more closed than open when it comes to European oncology specialty recognition. As
we come up to ten years since the revised Professional Qualification Directive came into being, it is
time for a review of its effectiveness in the field of healthcare professional qualification recognition.
The strategic importance of healthcare for every citizen, and the critical need to support European wide
health system resilience, more than make the case for healthcare professional qualification recognition
systems to merit special attention.

Finally, a major features of the early part of the next European Commission 2024–29 will be ongoing
Parliamentary scrutiny of the European Commission’s proposed reforms to EU pharmaceutical legislation.

Included within the Commission’s proposal is a recalibration of incentive structures to place additional
onus on the development of new treatments that meet unmet medical need. The application of a too
narrow definition of ‘unmet medical need’ in EU pharmaceutical legislation could have unintended
consequences, such as disincentivising development of certain medicines. Examples include efforts
to make treatment more tolerable, reducing side effects, and improving safety. As a core principle, any
application of ‘unmet medical need’ requires the confidence of patient and caregiver communities
and needs to reflect what is most important to them. To achieve that confidence a clear process for
consulting and being advised by scientific, medical, healthcare professional and patient organisations
in the application of the definition should be committed to and constructed.

Beyond this, in respect to medicines shortages, changes proposed by the Commission aim to help mitigate
shortages when they occur, providing additional powers and structures for the European Medicine Agency
and European Commission to conduct coordinating and oversight roles. However, the root causes of
medicines shortages are a combination of regulatory, manufacturing and quality, economic and supply
chain factors. With this in mind, the currently proposed amendments to EU pharmaceutical legislation
alone will not achieve the longer-term resolution required. Additional needs include for:
• A stronger maintenance of buffer stocks by manufacturers for any unforeseen problems in production;
• Better support of medicines production within the EU;
• Including supply obligations as part of procurement arrangements;
• Improving supply chain visibility, including through digitisation and automation of medication
management systems; and,
• Supporting the ability of pharmacies to compound medicines in scenarios of acute shortage.