



THE VALUE OF INNOVATION IN ONCOLOGY



EUROPEAN
**CANCER
PATIENT
COALITION**

Produced in collaboration with



2017

THE VALUE OF INNOVATION IN ONCOLOGY



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2017

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LIST OF KEY ABBREVIATIONS

ECPC	European Cancer Patient Coalition
EMA	European Medicines Agency
ESMO	European Society for Medical Oncology
EU	European Union
EUnetHTA	European Network for HTA
HTA	Health technology assessment
OECI	Organisation of European Cancer Institutes
QoI	Quality of life
WHO	World Health Organization

FOREWORD



This “*Value of Innovation in Oncology*” white paper outlines public health policy solutions to ensure that more people with cancer have access to cancer innovations. This new white paper facilitates evidence-based decision making and encourages inter-sectorial collaboration to access to medicines and technologies.

Each year, over three million Europeans are diagnosed with cancer, and over one million Europeans die from the disease. With a growing ageing population, action is urgently needed to address this major global health and societal concern. The white paper was developed to help policy-makers understand the ways in which they can improve access to innovative cancer care and treatment.

We produced this report so that policy makers, policy implementers and patient advocates would have a complete and accessible summary of the policy recommendations needed to encourage innovation in oncology. The European Cancer Patient Coalition is very grateful to our members and the ECPC Scientific Committee in helping to bring it to fruition.

Prof. Francesco De Lorenzo
President
European Cancer Patient Coalition

EXECUTIVE SUMMARY

1. INTRODUCTION

Innovative healthcare technologies, strategies and services offer the potential to save, improve and extend the lives of millions of people diagnosed with cancer each year. Ensuring that effective innovations are accessible in a timely and affordable manner to all patients is a challenge facing all stakeholders in cancer care. New approaches to both cancer policies and care delivery issues will be vital to ensure that innovations improve patient outcomes without increasing disparities. As we have continuous innovation in cancer research, diagnosis and treatment, so we also need innovation in cancer policies and care delivery.

To be meaningful for patients, innovation should aim to:

- **Promote patient-centred, multidisciplinary care** that makes optimal use of all therapeutic modalities
- **Improve upon existing care**, improving quality of life as well as extending life
- **Reduce inequalities** in care.

This paper presents the position of the European Cancer Patient Coalition (ECPC), in partnership with Interel, on the value of innovation in oncology today, focusing on issues that would benefit most from the direct involvement of patients. The objective is to present key factors affecting access to innovation in oncology in Europe and to propose key recommendations on how to improve equity in access and to actively involve patients in decision-making. It aims to inform both policymakers and cancer patients.

2. MAIN SYSTEMIC BARRIERS TO ACCESS TO INNOVATION IN ONCOLOGY

Each type of cancer has its own specific barriers to the creation, implementation and access to meaningful innovation. However, ECPC recognises several systemic obstacles that affect all European cancer patients. These barriers represent the key policy topics on which European and national decision-makers must act. These are: 1) Low health expenditure on cancer, relative to its high contribution to the total disease burden; 2) High cost of innovative treatments; 3) Complex regulatory and reimbursement pathways; 4) Lack of enabling environments; and 5) Limited patient involvement in decision-making.

3. IMPROVING ACCESS TO INNOVATIVE MEDICINES

Many cancer patients in the European Union (EU) have insufficient access to life-saving innovative cancer medicines. To ensure better and more equitable and sustainable access to innovative medicines of value, ECPC recommends that EU and national policy makers work on four main areas: the development and approval of new drugs, health technology assessment (HTA), pricing and cancer registries.

Development and approval of new drugs

Clinical trials identification and results

For many patients, clinical trials are the only opportunity to access innovative medicines. To help improve access to trials:

- The European Commission and other stakeholders should work to increase transparency by publishing all trial results, in line with the AllTrials campaign.
- The European Commission and other stakeholders should support independent efforts (by academia, research organisations, cancer patients' associations) to produce an unbiased, pan-European database on clinical trials in oncology to help patients identify and access them.

Fast-track approvals

The conventional EU regulatory framework is not optimal for many innovative treatments, such as personalised medicines and treatments for rare cancers. In principle, ECPC supports the adaptive pathways concept developed by the European Medicines Agency (EMA). However, EMA should increase transparency in the management of adaptive pathways, increase patient involvement and ensure that results are publicly reported in a timely manner.

- The European Commission should promote the safe use of fast-track approvals for better defined unmet needs, to be identified in partnership with cancer patients' organisations.
- The European Medicines Agency should improve the transparency and involvement of all stakeholders in the development of fast-track approval models, including adaptive pathways.

Transparency directive

Member States often fail to abide with the 180-day threshold imposed by the Transparency Directive (89/105/EEC), by which they are obliged to communicate reimbursement and pricing decisions on new medicines approved by the EMA. Therefore, we recommend that:

- The European Commission should strengthen the implementation of the Transparency Directive, in particular the 180-day time limit for EU Member States to implement pricing and reimbursement decisions on innovative medicines.
- The European Commission and all Member States should continue to engage with patients and other stakeholders to explore new models to update and perfect medicines' approval at the European and national levels.

Patients' involvement in R&D and approval

Patients should be involved throughout the life-cycle of all new cancer medicines. ECPC welcomes the progress made by the EMA in increasing patients' participation in regulatory processes. However, ECPC believes that patients should be invited to have routine input into regulatory processes, not merely to meet specific perceived needs for information. Thus, we recommend that:

- Patients should be routinely involved in further collaborations with regulators, academia and industry in the design and operation of regulatory models for innovative cancer medicines.

Integrating quality of life in oncology clinical trials

ECPC strongly believes that innovative medicines should be assessed on their impact on quality of life as well as survival and that real-world studies are essential. Thus, we recommend that:

- Quality of life should be a mandatory endpoint for all Phase 2 and 3 clinical trials in oncology.
- Real-world studies should be an integral part of the development of new cancer treatments, and should include patient-reported outcomes.

Health technology assessment

HTA is a multidisciplinary evaluation of the medical, economic, social, and ethical issues associated with the usage of a health technology. It is often used to inform decisions about pricing and reimbursement, and can promote innovation that delivers better outcomes for patients and society. ECPC has led a campaign to support increased harmonization on HTA across Europe, and for patients and their representatives to be formally and routinely included in HTA policy and operations.

We recommend that:

- EU and Member States decision-makers must define an ambitious political plan to continue harmonising HTA at the European level.
- There should be a centralised, relative effectiveness assessment that is valid, binding and directly implemented in all EU Member States and which considers patient-reported outcomes.
- Patients and their representatives should be formally and routinely included in HTA processes at European and national levels.

Pricing

EU cooperation on HTA and a more efficient implementation of the Transparency Directive could effectively reduce delays in access to innovative medicines. However, the broader issue of the affordability of new cancer medicines relates to the economic and financial situation at Member State level. We recommend that:

- Reimbursement and pricing mechanisms for innovative medicines should be aligned with improving health outcomes, including pay-for-outcome models.
- Member States should co-operate further on innovative approaches to information sharing, transparency, horizon scanning, joint price negotiation and procurement initiatives, with EU support.
- Patients should be routinely involved in pricing decision-making.
- The EU and Member States may need to consider fundamentally different financing and development models for cancer medicines.

Cancer registries

Disease registries are very important for the collection of real-world data on disease burden, the effectiveness, safety and cost-effectiveness of innovative treatments, service provision and care quality. Barriers to the optimal use of registries include variations between Member States in data quality and collection and in electronic health record coverage, limits on data sharing, fragmented support and lack of sustainable funding. We recommend that:

- The European Commission should promote the harmonisation of national cancer registries, and propose plans for the centralisation of the registries at the European level.

4. BEYOND MEDICINES: PROMOTING WIDER INNOVATION

Many forms of innovation can offer benefits for patients, healthcare systems and societies. Digital health technologies, service model, educational approaches, as well as non-drug treatments and diagnostic approaches are crucial in delivering equitable and sustainable access to innovative technologies and procedures in oncology. However, these benefits will not be realised unless health systems are enabled to adopt them.

- Member States should co-operate, with EU support, on means to optimally assess, reimburse and scale up innovative health technologies other than medicines, according to a patient-centred, evidence-based approach.
- Patients should be supported to play a greater role at all stages of research into all innovative approaches to cancer care.

Improving access to innovative diagnostics

Early detection of cancer is desirable since it allows earlier treatment and often results in longer survival and improved quality of life and has a positive impact on sustainability of healthcare systems. All cancer patients should have access to early diagnosis followed by high-quality treatment. There is a need for innovative diagnostic tests that are sensitive, fast, inexpensive, non-invasive and have a low false positive rate (i.e. high specificity). Data from clinical trials and real-world evidence should be used to improve the sensitivity and specificity of new diagnostic methods and biomarkers as well as to better understand the value of these tests to cancer patients.

The uptake of new diagnostic technologies will depend not only on regulatory approval, but also reimbursement and evidence both from trials and real-world studies. Thus, we recommend that:

- National governments should promote the uptake of innovative diagnostic technologies by implementing European regulatory frameworks to favour their reimbursement, when supported by consistent clinical data.
- The European Commission and the European Council should promote patients' and physicians' literacy on biomarkers and other innovative diagnostic tools available.

Improving access to radiation oncology

Around half of all patients diagnosed with cancer would benefit from radiation oncology at some point during their treatment, making radiotherapy a crucial pillar of cancer treatment. However, on average around one in four patients do not receive the radiation oncology treatment they need and significant variations exist across Europe in patients' access to modern services. The key innovation needed in radiation oncology pertains to investment models that deliver access to high-quality radiation oncology. Investment in radiation oncology services is essential and should take a long-term perspective. We support the following positions:

- Every cancer patient in Europe who would benefit from radiation oncology treatment should have access to as part of an individualised, multidisciplinary approach.
- To help overcome disparities in access, radiation oncology should be positioned within care models – and reimbursed – according to a patient-centred, evidence-based approach.
- Investment is necessary both in radiotherapy equipment and the training of radiation oncology healthcare professionals.

Improving access to innovative surgery

Surgery is one of the most effective treatment options for many solid tumours, and is best conducted by well-trained surgeons in the early stages of disease. The main factor impeding access to safe and affordable cancer surgery is the scarcity of adequately trained surgeons. Therefore, we recommend that:

- New approaches to teaching and training next-generation surgical oncologists must be quickly implemented into educational programmes throughout Europe.
- National cancer control plans must include the strengthening of surgical systems through investment in public sector infrastructure, education and training.
- Low-resource countries should be encouraged to partner with other countries that offer surgical oncology fellowships to improve the training of oncologic surgeons, to help standardise high-quality treatment plans.

Cancer surgery has improved over time, with the introduction of innovative instrumentation and techniques. With respect to this progress, we recommend that:

- New surgical approaches should be adequately tested and validated, properly implemented into educational programmes together with appropriate safety precautions.
- In the development of innovative surgery, the focus should be on longevity, long-term survival, quality of life and full integration with multidisciplinary treatment.

Improving the organisation of care and patient pathways

Cancer patient pathways provide guidance to primary health professionals and centres by outlining well-defined sequences concerning clinical suspicion of cancer, diagnosis, treatment and care. Patient pathways are designed to optimize logistics, reduce the time for diagnosis and treatment,

and improve patient outcomes. ECPC is working with the Organisation of European Cancer Institutes (OEI) to improve patient care pathways. We recommend that:

- The performance of standardised cancer patient pathways should be carefully monitored, and successful strategies should be implemented into national cancer plans.

Disinvestment

Disinvestment is the practice of continuously re-evaluating healthcare practices to identify which are delivering sufficient value to patients at the best possible cost-effectiveness ratio, and re-directing resources accordingly. From the patients' perspective, the main objective of disinvestment should be to save and redirect resources to ensure patients' access to meaningful and affordable innovation.

- Every effort should be made to ensure that patients' voices are heard throughout the health policy process and that these processes are designed to allow patients to contribute to the identification and removal of low value and inappropriate care.

Enabling the eHealth and mHealth evolution

eHealth and mHealth represent evolutions of care systems, whereby information communication technologies are applied to care pathways, facilitating the collection and elaboration of patients' data for a variety of purposes. ECPC strongly believes that implementing a solid European eHealth infrastructure and boosting the development of mHealth tools could benefit healthcare systems in terms of efficiency, cost-effectiveness, patient empowerment and system evaluation.

The primary obstacles for the implementation of eHealth services are interoperability, a lack of supporting evidence and the need for innovative payment models.

- The European Commission should promote, develop and implement eHealth specific standards to harmonise the deployment of innovative eHealth solutions.
- Member States should promote and implement research projects and pilots to gather evidence on the cost-effectiveness of eHealth tools
- Member States, in close collaboration with the European Commission, should explore innovative payment model to seamlessly implement innovative eHealth solutions within new care pathways.

Key issues in the development of effective mHealth apps relate to the safety of patients' data and the quality and efficacy of apps. Data protection is important and is achievable with simple safeguards, and privacy concerns should not obstruct valuable innovation in mHealth.

We recommend that:

- The European Commission and all stakeholders involved in the drafting of the Code of Conduct on privacy for mobile health applications must ensure a solid implementation of the Code.
- Patient consent should be gained using a short, simple statement without legal jargon, such as those provided in the European Commission's Code of Conduct on privacy in mHealth apps.

- Apps should be patient-centred by design and by default, hence ECPC favours the involvement of patients from the early stage of development onwards.
- Apps should provide correct and reliable information from cited and reputable sources. Collaboration with medical societies may be helpful to check the validity of the sources.
- Options should exist for app developers (especially in academia) to collect anonymised data for research purposes.
- National-level pathways for the assessment and reimbursement of digital health innovations require clarification and support.

5. CONCLUSIONS

Innovative healthcare technologies, strategies and services offer the potential to improve the lives of many people living with cancer. Ensuring that effective innovations are accessible and affordable to all patients is a challenge facing all cancer stakeholders.

The successful development and implementation of new cancer care modalities stems from putting the needs of patients at the centre of the innovation process. Patients are the ultimate beneficiaries and users of cancer diagnosis, treatment, and care. They have unique knowledge, perspectives and experiences that improves and encourages innovation in oncology. Optimal innovation can only be obtained by understanding the diverse needs and preferences of cancer patients, and integrating patient-centred approaches into the regulatory and healthcare system.

1. INTRODUCTION

Innovative healthcare technologies, strategies and services offer the potential to save, improve and extend the lives of millions of people diagnosed with cancer each year. Ensuring that effective innovations are accessible in a timely and affordable manner to all patients is a challenge facing all stakeholders in cancer care.

This paper presents the position of the European Cancer Patient Coalition (ECPC), in partnership with Interel, on the value of innovation in oncology today, focusing on issues that would benefit most from the direct involvement of patients.

The objective of the paper is to present key factors affecting access to innovation in oncology in Europe and to propose key recommendations on how to improve equity in access and to actively involve patients in decision-making.

This paper aims to inform both policymakers and cancer patients. On one hand, ECPC requests that European, national and regional policymakers implement the recommendations set out in this document and to use them as a guide for the meaningful implementation of innovative treatments in the territory of their competence. On the other hand, the document also aims to help national and local patients' organisations to focus their energies on key aspects of innovation, identifying a variety of issues and gate-points for action.

The European Cancer Patients' Bill of Rights (2014) asserts the right of every European citizen to optimal and timely access to appropriate specialised care, underpinned by research and innovation.¹ ECPC firmly believes that the latest innovations in diagnosis and treatment should be made available to all European cancer patients who would benefit from these, following relevant regulatory approval.

From a public health perspective, cancer care is rightly a principal target for innovation, being the second leading cause of mortality and morbidity in Europe. Cancer caused around 1.4 million deaths across the European Union (EU) in 2016,² equivalent to one in four of all deaths.³ Its incidence is rising, and by 2025 over 3.1 million cancer cases will be diagnosed annually across the EU.⁴ As well as enormous healthcare costs, estimated at €87.9 billion in 2014,⁵ cancer also incurs substantial indirect costs through early death, disability, lost working days and informal care.^{6,7}

Rapid advances in the understanding of cancer are fuelling a revolution in personalised cancer medicine that can deliver enormous value to patients, healthcare systems and societies. Indeed, most of the noteworthy therapeutic innovations in 2015 were cancer treatments.⁸

However, innovation in cancer is not only innovation in cancer medicines. The often-overlooked broader cancer patients' pathway involves a plurality of treatment strategies and professionals, each with their own issues related to the identification, approval and access to meaningful innovation. This paper focuses on all key aspects of innovation in oncology, underpinned by the principle that the final objective of all innovation in cancer is to cure patients.

1.1 WHAT IS MEANINGFUL INNOVATION FOR CANCER PATIENTS?

The personalised medicine revolution changed the way that cancer is fought by changing the way the disease is understood. It is now known that cancer is not a single disease, but rather a group of many different conditions. Therefore, there cannot be a single definition of innovation for all cancers and for all cancer patients.

However, ECPC recognises that there are general considerations common to all cancer patients. To be meaningful for patients, innovation should aim to:

Promote patient-centred, multidisciplinary care⁹ that makes optimal use of all therapeutic modalities - including medicines, radiation oncology and surgery - together with diagnostic, prognostic and screening technologies. Truly multidisciplinary care is underpinned by novel and effective enabling systems, including patient-centric care pathways, service delivery models, education methods, patient empowerment approaches, digital infrastructure and financing that are necessary to realise the benefits of novel technologies.

Improve upon existing care. Innovation is not meaningful unless it adds benefit. Specifically, innovative cancer care approaches should aim to improve the quality of life (QoL) of patients, as well as to extend life (also see p. 26). Better disease management through innovative approaches may also improve the efficiency of healthcare systems by preventing the need for other - often expensive - services such as hospitalisations and additional procedures. However, this must be carefully evaluated.

Reduce inequalities in care. Introducing innovative technologies must not create new inequalities, but rather should help curb the existing ones. Wide disparities exist between and within European countries in access to innovative care, as highlighted in the ECPC Position paper "*Challenging the Europe of disparities in cancer*"¹⁰ and other reports.^{5,11-15} A recent analysis by the European Society for Medical Oncology (ESMO) identified 'large and clinically significant differences in the formulary availability, out-of-pocket costs and actual availability for many anticancer medicines in Europe'.¹¹ The disparities were greatest in Eastern Europe and related in particular to expensive treatments for incurable cancers. Important variations and inequities also exist in access to quality and innovative surgical procedures and state-of-the-art radiation oncology.¹⁶⁻¹⁸ Innovation approaches to cancer care must therefore be developed and implemented in ways that address, rather than exacerbate, existing inequalities in care.

New approaches to cancer policies and care delivery will be vital to ensure that innovations in cancer care improve patient outcomes without increasing disparities. As we have continuous innovation in cancer research, diagnosis and treatment, so we also need innovation in cancer policies and care delivery.

1.2 WHY A PAN-EUROPEAN PAPER ON THE VALUE OF INNOVATION?

Any European citizen would concur that national and regional authorities play a crucial role in the way cancer care services are provided to them, including innovative treatments and care pathways. The complexity of cancer care today is such that very few of the problems that ECPC Members experience in their daily work with patients are completely detached from European policies, regulations, or initiatives.

The added value of a pan-European approach to innovation resides in its ‘helicopter view’, that allows the larger trends and European issues to be grasped and adapted to local specificities. This is also confirmed and reiterated in the Treaty on the Functioning of the EU, which explains how public health policies are regulated at the EU level. 19 Article 168 states:

‘1. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.

Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.’

Public health is therefore among the competence areas shared between Member States and the EU. Accordingly, the principles of subsidiarity and proportionality are applicable to public health issues. Subsidiarity is the principle whereby the EU does not act (except in the areas that fall within its exclusive competence), unless it is more effective than action taken at national, regional or local level. Proportionality requires that any action by the EU should not go beyond what is necessary to achieve the objectives of the Treaties.

In line with the definitions of subsidiarity and proportionality, EU Member States are responsible for the defining their health policies and for organizing, delivering, managing and resourcing their health services. EU actions complement national policies in the shared competence area of public health.

However, there are key areas in which the pan-European concerted actions can provide better value to patients, for example:

- improving public health
- preventing physical and mental illness, and the sources of danger to physical and mental health
- fighting major health epidemics by promoting research into their causes, transmission and prevention
- health information and education
- monitoring serious cross-border threats to health, issuing alerts and combating such threats.

ECPC strongly believes that increasing cancer patients' access to innovative treatments falls within the objective on improving public health. Therefore, according to subsidiarity and proportionality principles, we strongly believe that the European Commission is fully entitled to intervene in this domain.

This policy paper is based on the aforementioned assumptions and calls for an increased level of collaboration among the EU institutions and national decision-makers as a precondition for the fruitful engagement of all stakeholders affected by and/or involved in the issue of access to innovation in oncology.

1.3 STRUCTURE OF THE PAPER

In Chapter 2, 'Main systemic barriers to access to innovation in oncology' we describe the key macro-issues that limit all patients' access to innovation, to varying degrees across Europe, and which would benefit from a pan-European, patient-centred approach to their solution.

Chapter 3, 'Improving access to innovative medicines', dives into the specific problems related to development, approval, pricing and reimbursement of cancer drugs.

Chapter 4, 'Beyond medicines: promoting wider innovation' stresses the need to shift the focus from discussing only about innovation in cancer drugs, towards a more holistic, multidisciplinary concept of innovation that also encompasses diagnostics, radiotherapy, surgery, care organisation and pathways, and eHealth/mHealth.

1.4 METHODOLOGY

'*Value of Innovation in Oncology*' has been written by ECPC with the active support and contribution of Interel. The document enjoyed the support and supervision of the ECPC Board of Directors, and the contribution of the ECPC General Assembly, which was consulted on the main topics of this paper in June 2016 during a dedicated, open session at the Annual General Meeting in Brussels.

'*Value of Innovation in Oncology*' is based also on a systemic literature review, to substantiate the policy recommendations with unbiased and reliable evidence (see References). The paper expresses the independent view of ECPC and was developed in collaboration with Interel.

'*Value of Innovation in Oncology*' was funded by unrestricted grants from Eli Lilly, Bristol Myers Squibb, Merck and Pfizer. ECPC shared advanced drafts of the content of the paper with the funders. However, the content of the paper was not influenced by the funders and ECPC retained full editorial control over its content.

2. MAIN SYSTEMIC BARRIERS TO ACCESS TO INNOVATION IN ONCOLOGY

Each type of cancer has its own specific definition of value and specific barriers to the creation, implementation and access to meaningful innovation, since each is treated differently and affected by different factors.

Nevertheless, ECPC recognises several systemic obstacles to access to meaningful innovation, which affect all European cancer patients. These barriers represent the key policy topics on which European and national decision makers must intervene to facilitate equitable and sustainable access to meaningful innovation in oncology to all European cancer patients.

2.1 LOW HEALTH EXPENDITURE ON CANCER

The unduly small proportion of healthcare spending dedicated to cancer is a fundamental obstacle limiting patients' access to innovation. Cancer represents the first cause of preventable death in 17 out of 27 EU Member States.²⁰ Even when cancer does not kill, it still heavily impacts our society. Cancer confers the second largest disease burden in Europe, accounting for 19% of all disease (measured by disease-adjusted life years lost).⁵

Notwithstanding these figures, EU Member States invest only 4-6% of their healthcare budgets on cancer, a stable proportion that does not reflect the major, and rising, contribution of cancer to the total disease burden.^{5,6} This unacceptable imbalance in cancer expenditure is exacerbated between EU Member States (Figure 1 and Figure 2) and this is reflected in inequalities in survival outcomes.^{5,21} Increased healthcare spending on cancer is associated with improved survival⁵ and evidence suggests that cancer is a disease favoured by the public for investment in innovation.²² Accordingly, ECPC urges policymakers to invest in cancer services in accordance with its impact on patients and society.

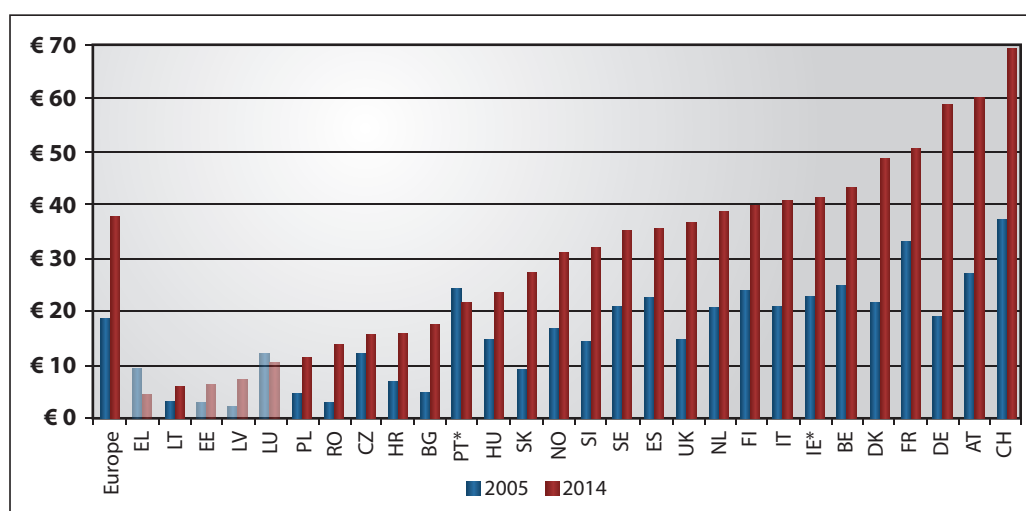


Figure 1. Annual average growth rates in total health expenditure and cost of cancer drugs (in 2014 prices) between 2005 and 2014. Reproduced with permission from Jönsson et al.⁵

Notes: Hatched bars indicate that data for cancer drugs for EE, LV, LU, and EL only comprise retail sales.

*Both growth rates in IE are between 2006 and 2014, and in PT between 2010 and 2014. There is no growth rate of the cost of cancer drugs in CY, LV, and MT owing to a lack of data.

2.2 HIGH COST OF INNOVATIVE TREATMENTS

Several EU stakeholders (e.g. ESMO¹¹) have reported that the high prices of innovative cancer medicines are a principal barrier to access, culminating with the ground-breaking Council of the EU Conclusions of 2016.²³ The total cancer drug sales in Europe reached €19.8 billion in 2014, having more than doubled since 2005 owing to the rising incidence of cancer, increased survival rates and the increase in the cost of new medicines.⁵ Access to treatments varies even between countries with similar economic power, suggesting an additional role of policy factors.⁵ The cost of new medicines should be weighed in relation to the overall healthcare financial situation and, most importantly, on the added value they bring to patients and societies.

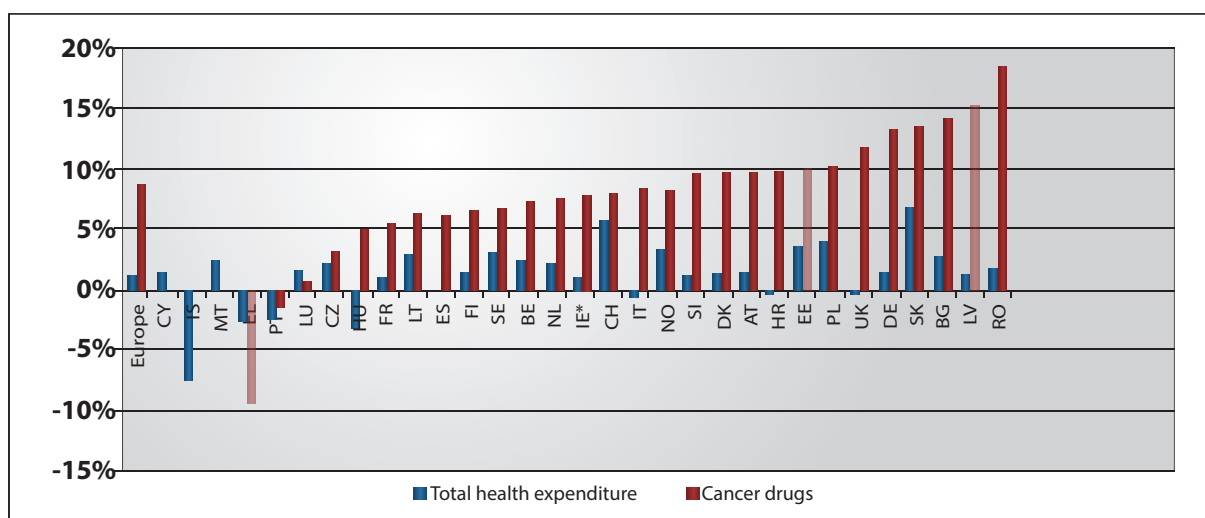


Figure 2. Cost of cancer drugs per capita (in 2014 prices), 2005–2014.
Reproduced with permission from Jönsson et al.⁵

Notes: Hatched bars indicate that data for EE, LV, LU, and EL only comprise retail sales.

*The value for 2005 for IE is from 2006 and for PT from 2010. CY, IS, and MT are missing due to lack of data.

2.3 COMPLEX REGULATORY AND REIMBURSEMENT PATHWAYS

Variations and delays in the EU and national procedures for approval, assessment, reimbursement and pricing of new medicines^{12–14,24} can lead to unacceptable loss of life for patients with cancer. Each cancer medicine must first be approved by the European Medicines Agency (EMA), and then each country must conduct its own assessment and negotiation on pricing and reimbursement. This is done more than 50 times over, as several EU countries have regional pricing and reimbursement assessments. There is a substantial gap between the high speed at which new innovative treatments are becoming available, and the lengthy review procedures to determine that an innovative treatment is cost-effective and should be reimbursed.^{13,14}

2.4 LACK OF ENABLING ENVIRONMENTS

The benefits of innovation will not be realised unless healthcare systems and patients can employ them optimally and sustainably at a large scale. In this perspective, the collaboration between patients' associations and cancer institutes is crucial to ensure that patients are kept at the centre of decision-making concerning their health, particularly in ever-changing and innovating healthcare services.

Pan-European harmonisation is happening in every aspect of cancer care, such as treatment guidelines, medicines' approval, organisation of care guidelines. However, there have been no attempts to provide a framework to better develop the relationships among patients, patients' organisations and cancer centres, which can dramatically influence the way services are delivered to patients and therefore impact their QoL and overall experience in the cancer centre.

ECPC has partnered with the Organisation of European Cancer Institutes to produce the first European, patient-centric method to guide patients' organisations and cancer institutes towards better collaboration. Provisionally titled 'Solving Issues, Building Relationships', this method will be published during the European Cancer Congress in Amsterdam (2017). It fills a gap in cancer care and research and responds to the increasing demand for guidance and support to help better involve patients in the life of the cancer centre.

The main mission of 'Solving Issues, Building Relationships' is to give guidance to patients, patients organisations and cancer institutes on how to solve problems affecting patients in the cancer centres, and therefore build better relationships to support everyone's needs and rights. The methodology and preparation of 'Solving Issues, Building Relationships' will be underpinned by a scientific paper in the field of ethics and organisation management.

2.5 LIMITED PATIENT INVOLVEMENT IN DECISION-MAKING

Cancer patients are only marginally involved in the definition of research priorities and in decisions about the implementation (including pricing and reimbursement) of innovative treatments. This situation is unacceptable, as cancer patients are the ultimate users and beneficiaries of these innovations.

The complexity of cancer treatment and the specific risk-benefit ratios for each cancer type demand a greater involvement of patients and their advocates, who are uniquely positioned to bring to the decision-making process the direct experience and perspective of those facing the diseases. Therefore, patients must be integral to decisions involving measures to achieve timely, equitable and sustainable access. This general principle is valid not only to empower individual patients within their own care, but also in driving wider improvements. Patients and patients' organisations should work in partnership with healthcare professionals, researchers, healthcare system managers and health ministries in the development, assessment and introduction of innovative cancer care technologies. To facilitate a seamless integration of patients and their representatives in the decision-making processes on health, policies should make resources available to be invested in improving cancer literacy of patients, caregivers and citizens. Higher health literacy levels help to improve lifestyles and earlier diagnosis and promote better adherence to treatment, according to the World Health Organization (WHO).²⁵

3. IMPROVING ACCESS TO INNOVATIVE MEDICINE

All new drugs for cancer must be authorised by EMA, based on evaluation of safety and efficacy data from clinical trials, before they can be marketed in the EU. Member States then decide which medicines are reimbursed by their health systems, and at what price, trying to balance the goal of improving access to innovative medical technologies with the need to ensure the sustainability of healthcare systems and the efficiency of care. Many Member States use Health Technology Assessment (HTA), a determination of the therapeutic value of innovative medicines for patients, healthcare systems and societies, to inform their decisions on reimbursement and pricing.

In this scenario, many EU cancer patients still cannot access life-saving innovative medicines.

Examples:

- **Melanoma:** Over 5000 patients with metastatic melanoma in Europe are denied access to new, life-saving drugs every year, as estimated by a recent study that reported unacceptable differences in access to these medicines across Europe.¹⁵ At least 70% of patients with metastatic melanoma in Western Europe were treated with innovative medicine, while only 41% of patients in Central Europe and only 10% in South and Eastern European countries had access to these treatments. The study estimated that at least 5000 Eastern and Southern European patients with melanoma did not have access to innovative medicines that could save their lives.¹⁵

- **Breast cancer:** For a drug like trastuzumab, which targets the ERB2 receptor and has led to a new standard of care for aggressive breast cancer, there are marked differences in time to approval/reimbursement across EU Member States. Since 2015, trastuzumab has been included in the WHO list of essential cancer drugs. The drug was available to patients in the Netherlands, Germany and Sweden immediately after the market authorisation. In contrast, 5 years passed before patients in Bulgaria could access trastuzumab and even longer delays occurred elsewhere - 6 years in Denmark, 7 years in Romania and Hungary, 10 years in Slovakia and more than 12 years in Latvia. In 10 out of 28 EU countries it took 2 years or more to provide trastuzumab to patients in metastatic setting, further demonstrating the unacceptable delays in access to this essential cancer drug.

- **Not only oncology:** A 2013 report²⁶ provides more examples not only related to oncology: 'Lower income Eastern and Southern European countries tend to face longer delays than their Western and Northern European counterparts. At the extremes, Portugal had the wait an average of 46 months for new oncology drugs after they were released elsewhere in Europe. Switzerland (not an EU member) and the Netherlands had to wait just 5 months. For diabetes drugs, Croatia had the longest delay at 37 months, while Switzerland again had to shortest delay of just one month and five wealthy EU Member States waited only about two months.'²⁶

To ensure better, more equitable and more sustainable access to innovative medicines of value, ECPC recommends EU and national policymakers to work on four main areas:

- Development and approval of new drugs
- HTA
- Pricing
- Cancer registries.

3.1 DEVELOPMENT AND APPROVAL OF NEW DRUGS

CLINICAL TRIALS IDENTIFICATION AND RESULTS

ECPC welcomes the revised EU Clinical Trials Regulation intended to facilitate international clinical trials and improve transparency and access to results.²⁷ While we understand that specific product discussion might need to remain confidential before marketing authorisation, we fully support the concept of enhanced transparency in sharing the results of clinical trials, in particular of negative trials results, in line with the AllTrials petition *signed by ECPC* in 2014. Effective, harmonised, EU-wide implementation and monitoring are essential to ensure it benefits all EU patients.

For many patients, particularly those with rare cancers, clinical trials offer the only opportunity to access innovative medicines.²⁸ Yet, only 5% of all eligible patients take part into a clinical trial and thereby profit from their added value. We believe that the problem resides in lack of information on the risks and advantages of participating in clinical trials. General information on trials provides little help to cancer patients because of the specific design of clinical trials in cancer. This information gap is widened by the lack of a centralised, harmonised global database of clinical trials in cancer - information on enrolment is scattered across clinicaltrials.gov, EudraCT and several other national databases. Each of these presents information in different ways, but most often they forget the basic need of patients for clarity.

ECPC recommends the European Commission, all Member States and all other stakeholders to promote the creation of a pan-European database of all cancer clinical trials, developed by independent actors (such as academia, research organisations such as the European Organisation for Research and Treatment of Cancer [EORTC] and patients' organisations) to provide unbiased, clear and harmonised information on all the clinical trials existing in oncology. ECPC and EORTC are investigating a possible collaboration to create a search engine capable of pooling information not only from Clinicaltrials.gov, but also from European and national databases. The unique aim of the ECPC-EORTC search engine will be to provide patients with understandable, simplified and harmonised information on all trials existing in the field of cancer. Our vision is to allow patients to search for trials based on their condition and knowledge of the disease, and to find useful data that they can share with their treating physicians.

The European Commission and other stakeholders should work to increase transparency on the results of clinical trials, by publishing all trials results, in line with the AllTrials campaign.

The European Commission and other stakeholders should support independent efforts (by academia, research organisations, cancer patients' associations) to produce an unbiased, pan-European database on clinical trials in oncology, to facilitate identification and access to clinical trials to all cancer patients who need it.

FAST-TRACK APPROVALS

The conventional EU regulatory framework is not optimal for many innovative treatments, such as personalised medicines and treatments for rare cancers, where challenges exist in the generation of sufficient clinical data. In recent years, EMA has developed various approaches to help support early access for innovative medicines that address unmet needs in cancer and other diseases. These include accelerated assessment and conditional marketing authorisation tools, the adaptive pathways concept, and the priority medicines scheme (PRIME). In its 'Strategy to 2020', EMA committed to reflect on additional support for beneficial innovation and expand opportunities to reduce evidence burden to *'ensure that regulation is never a hurdle or barrier to innovation taking into account the complexity of medicine development as well as the changing nature of pharmaceutical innovation.'*²⁹

In principle, ECPC supports the adaptive pathways concept, which builds on existing early access tools and involves a prospectively planned, iterative development plan for evidence generation, participation of all stakeholders, and the complementary use of real-world data. Anticancer drugs accounted for a substantial proportion of the submissions to the recent adaptive pathways pilot.³⁰ ECPC welcomes the integral role of patient involvement within the adaptive pathways approach, although in practice this has so far been limited. In the recent pilot, patient representatives only attended 4 out of 18 Stage II discussion meetings.

ECPC agrees with the recent Council of EU Conclusions whereby:

- 1) the eligibility conditions for early marketing authorisation schemes should be further clarified to improve transparency, ensure a positive benefit-risk balance, and to focus on medicinal products of major therapeutic interest for public health or to meet unmet medical needs of patients remove.
- 2) an evidence-based analysis should be performed to assess the impact of EU regulatory instruments on innovation and access, among other issues.²³

ECPC believes that the experience of EMA, and the quality of its work, will allow it to strike the right balance between introducing a new variable of risk in clinical trials and the potential benefits for the larger cancer patient population. The key factor will be ensuring that EMA improves the process of implementation and public scrutiny of the adaptive pathways pilots. EMA should increase transparency in the management of adaptive pathways by:

- Instituting a more robust involvement of stakeholders in strategic goal-setting, particularly regarding the identification of unmet medical needs (via patients' advisory groups, public consultations, stakeholder meetings).
- Ensuring that the main results from clinical trials are publicly reported within 12 months of their completion, via the EU and/or WHO register sites.

The European Commission should promote the safe use of fast-track approvals for better defined unmet needs, to be identified in partnership with cancer patients' organisations.

The European Medicines Agency should improve the transparency and involvement of all stakeholders in the development of fast-track approval models, including adaptive pathways.

TRANSPARENCY DIRECTIVE

The current European legal framework (and its implementation) are insufficient to ensure that cancer patients have timely access to meaningful innovation. Irrefutable data show that Member States systematically fail to abide to the 180-day threshold, imposed by the Transparency Directive (89/105/EEC), by which they are obliged to communicate reimbursement and pricing decisions on new medicines approved by EMA (see p. 22).

We believe that the EU needs to better implement and enforce this rule, to guarantee fast and accountable decisions from Member States on new medicines. While the Directive served as the primary effort to harmonise pharmaceutical policies in Europe, it is now becoming outdated. The update of the Transparency Directive, halted in 2015, effectively deprived the European Parliament and all EU stakeholders of a key possibility to shape the future of healthcare in Europe. ECPC would welcome further engagement by the European Commission towards the production of a new Transparency Directive first and foremost transforming it into a Regulation to ensure the proper legal adaptation at the national level. In this light, ECPC has supported important amendments³¹ to the own initiative report on access to medicines, produced within the Environment, Public Health and Food Safety (ENVI) Committee of the European Parliament, to trigger a debate on the future of medicines' development and accessibility.

However, we are conscious of the unfavourable political scenario that was ultimately responsible for the failure of the Commission's proposal for a new transparency Directive. In this sense, we call on the European Commission to focus its energies on strengthening the implementation of the Transparency Directive in its current form, by acting to sanction those countries that are failing to comply with it. In the long term, we hope that the European Commission and Member States will fruitfully engage with patients and other stakeholders to update the existing legal framework related to drug development in Europe.

The European Commission should strengthen the implementation of the Transparency Directive, in particular the 180-day time limit for EU Member States to implement pricing and reimbursement decisions on innovative medicines.

The European Commission and all Member States should continue to engage with patients and other stakeholders to explore new models to update and perfect medicines' approval at the European and national levels.

PATIENTS' INVOLVEMENT IN R&D AND APPROVAL

Successful product development stems from putting the needs of patients at the centre of the innovation process.³² Patients should be involved throughout the life-cycle of all new cancer medicines, from early dialogue regarding investigational products, through approval, pricing, reimbursement, and other post-authorisation studies.

ECPC welcomes the progress made by EMA in increasing patients' participation in regulatory processes³³ and its encouragement of further efforts to incorporate patients' values and preferences into the scientific review process.²⁹ In particular, ECPC welcomes EMA's reflection that increased patient participation in the adaptive pathways process will assist in the selection of candidates for which accelerating access is particularly desirable, and to provide insights on feasibility and ethical aspects, and to support enrolment in clinical trials and registries.³⁰ However, ECPC believes that patients should be invited to have routine input into regulatory processes, not merely to meet specific perceived needs for information. Patients should be routinely involved in stakeholder meetings regarding the development of innovative treatments within the adaptive pathways and PRIME schemes.

ECPC has a leading role in the Patient Preferences in Benefit-Risk Assessments during the Drug Life Cycle (PREFER) study, which will develop evidence-based guidelines on how and when patient-preference studies should be performed throughout the development of new medical treatments. Patient preferences are concerned with measuring how patients value components such as treatment endpoints, route of administration, treatment duration, treatment frequency, frequency of side effects, price and QoL. PREFER will run from 2016-2021, funded by the Innovative Medicines Initiative.

Patients should be routinely involved in further collaborations with regulators, academia and industry in the design and operation of regulatory models for innovative cancer medicines.

INTEGRATING QUALITY OF LIFE IN ONCOLOGY CLINICAL STUDIES

Maintaining or improving QoL can allow many patients to return to work and hence, in conjunction with extended survival, it can confer economic benefit to both patients and society. QoL is also often a key component used to determine cost-effectiveness during the HTA processes that many countries use to determine the level of reimbursement of a treatment.

Despite its importance, QoL is not evaluated in the majority of clinical trials for new medicines. ECPC welcomes recent EMA guidance on the use of QoL and other patient-reported outcomes in clinical studies of cancer medicines.³⁴ Indeed, we believe that QoL should be consistently included as a secondary endpoint in all Phase 2 and Phase 3 clinical trials of oncology treatments.

QoL data must also be collected within real-world studies to ensure that new medicines provide value in real-life settings and conditions. ECPC agrees with recent statements by EMA authors that regulators could encourage trials that measure value to assist HTA bodies and reimbursement bodies in their assessments.³⁵ ECPC supports the implementation of real-world data studies to support market authorisation and HTA, provided that data on patient-reported outcomes such as QoL are collected.

Assessments of value and cost-effectiveness should be repeated over the lifecycle of the drug and different uses.⁵

Quality of life should be a mandatory endpoint for all Phase 2 and 3

Real-world studies should be an integral part of the development of new cancer treatments, and should include patient-reported outcomes.

3.2 HEALTH TECHNOLOGY ASSESSMENT

HTA can be instrumental in promoting innovation that delivers better outcomes for patients and society.³⁶ Key issues with existing HTA processes include:

Variation: HTA is not used by all EU Member States and, where it used, differences in processes and methods result in delays and variations in approval decisions and inequities in access.^{12-14,37,38} Member States are free to adopt their own pricing and reimbursement decisions, but reimbursement authorities are obliged to communicate a decision of whether a medicine will be reimbursed and at what price within 180 days of an application. In practice, reimbursement decisions for cancer medicines can be far slower and this varies greatly between countries (see p. 22). Such delays can lead to inequities in access and an unacceptable loss of lives. Higher healthcare policy performance and higher healthcare expenditure correlate with faster reimbursement decision-making and with reduced cancer mortality.³⁹ Various countries have implemented managed entry schemes help mitigate high prices and uncertainties in the evidence base for innovative medicines.^{12,14,40}

Limitations in data used for decision-making: HTA should involve a comprehensive evidence-based evaluation encompassing patient-reported outcomes (including QoL) and the wider economic implications of new treatments, in addition to survival outcomes. In practice, QoL data are included in only around one half of relative effectiveness assessments for anticancer medicines and have a limited impact on the recommendations.⁴¹ Other evidence suggests that considerations of the impact of interventions on health on economic growth have little or no impact on decision-making regarding reimbursement, principally owing to budget separation and a short-term focus.⁴²

Fundamentally, while EMA conventionally focuses on clinical trial data, payers may require HTA to evaluate real-world data on the relative effectiveness and cost-effectiveness of new medicines (compared with existing treatments) to assess their value within their own health system. This discrepancy can mean that HTA procedures are hampered by a lack of necessary data.⁴¹ An important consideration is that real-world data cannot be collected until after authorisation, under conventional approval procedures.

Lack of patient involvement: Very few HTA agencies involve patients in their assessments⁴³ and, where public engagement is sought, the approaches vary.^{44,45} Patient involvement in HTA is often at public consultations, in providing evidence and in appeals against decisions.⁴³ The level of influence and impact that patients have on decision-making is unclear, and may be limited. In some countries, HTA publications may not be made publicly available, meaning that they cannot be scrutinised and challenged by patients and other stakeholders.

Barriers to involving patients in HTA include a lack of established methods for providing patient evidence, a lack of agreement on when patient engagement is needed and most useful, and a lack of time and capacity among all parties.⁴³ Among EU HTA bodies, the National Institute for Health and Care Excellence in England (NICE) undertakes the most robust patient engagement scheme, although this does not guarantee access to innovative cancer drugs of value.¹²

Duplication: Parallel assessments by individual HTA bodies based on a common evidence base represents a wasteful duplication of effort and resources.

Thankfully, the European Commission and several EU Member States have already recognised the need to cooperate in the field of HTA. ECPC strongly supports EU efforts to promote co-operation and harmonisation in HTA via the HTA Network and European Network for HTA (EUNetHTA) Joint Actions. By March 2016, 20 joint assessments (three for cancer treatments) had been finalised and there was evidence of national-level uptake of EUNetHTA outputs.⁴⁶ ECPC welcomes the EUNetHTA Joint Action 3, including efforts to promote dialogue early in the development of innovation medicines and technologies between industry, regulatory, HTA and, where relevant, pricing bodies. EUNetHTA should be institutionalised into a new, permanent body and with a formalised collaboration with EMA.

ECPC also salutes the new comprehensive Directorate-General for Health and Food Safety inception impact assessment, *'Strengthening of the EU cooperation on Health Technology Assessment'*,²⁴ and will provide specific comments on this in a separate document.

The political will to keep harmonising HTA is crucial to ensure that real change is possible. We strongly believe HTA can become a great example of European cooperation, provided that national and European policymakers understand the hunger and deeply rooted needs for solid, binding harmonisation of HTA. ECPC would support ambitious political agendas which will put HTA harmonisation on top of the priorities for medicines development.

EU and Member States decision-makers must define an ambitious political plan to continue harmonising HTA at the European level.

ECPC strongly supports the establishment of an EU-wide relative effectiveness body to help reduce delays and variations in access and to avoid the wasteful duplication of effort and resources by individual Member States. This position was central to the ECPC-led campaign to support to amend Regulation 726/2004. ECPC welcomes the recent progress toward this goal by the European Parliament ENVI Committee to Regulation 726/2004 (governing the operations of EMA). We are also pleased to acknowledge the support of the European Commissioner for Health and Food Safety, Vytenis Andriukaitis, for the principles of the ECPC campaign and the outcome of the ENVI Committee.

Joint relative effectiveness assessments for cancer medicines could feasibly capture the content typically used for national or local assessments⁴⁷ and there is substantial commonality between EMA and some HTA bodies in terms of evidence requirements.⁴⁸ ESMO have published a Magnitude of Clinical Benefit Scale (ESMO-MCBS) to provide a rational, structured and consistent approach to ranking the magnitude of clinically meaningful benefits (based on clinical trial data) that can be expected from new anticancer treatments for solid tumours.⁴⁹ While these scales were developed without the support of patients or patient organisations, they include an assessment of QoL,

improvement in symptoms, and reduced toxicity, as well as survival-based outcomes.

There should be a centralised, relative effectiveness assessment that is valid, binding and directly implemented in all EU Member States and which considers patient-reported outcomes.

Patients must also be involved in HTA so that activities and decisions of HTA bodies have greater focus toward and relevance to the people most directly affected.⁵⁰ As the HTA International '*Values and quality standards for patient involvement in HTA*' state, patients have unique knowledge, can contribute essential evidence, and have the same rights to contribute to HTA as other stakeholders.⁵¹ ECPC invites the EUNetHTA Joint Action 3 and HTA Network to specifically consider how to increase patient involvement and input into HTA processes, an aspect lacking from the current strategy on EU cooperation.³⁶

Improving patient involvement in HTA requires:

- 1) Processes for patient involvement to be defined (through multi-stakeholder collaboration) and shared among European HTA agencies
- 2) HTA agencies to be adequately resourced (by Member States) and trained in best practices for patient engagement
- 3) Patient organisations to be supported (by Member States) to increase their capacity to participate in HTA (including both resources and education/awareness building).

ECPC supports transparency in HTA processes and reimbursement decision-making so that patients can scrutinise and, where appropriate, challenge decisions that affect them.

Patients and their representatives should be formally and routinely included in HTA processes at the European and national levels.

3.3 PRICING

EU cooperation on HTA and a more efficient implementation of the Transparency Directive can effectively reduce delays in access to innovative medicines. However, the broader issue of affordability of new cancer medicines relates to the economic and financial situation at the Member State level.

The official list prices of anticancer medicines vary widely across Europe, while the actual prices paid are unclear owing to confidential discounting.⁵² Most EU Member States negotiate a national price for new medicines using 'international reference pricing: i.e. based on the price in other countries. This leads to inefficiencies in the way prices are negotiated, leaving smaller and poorer EU countries with little negotiation leverage and therefore hampering these countries' capacity to access new medicines. Furthermore, national healthcare budgets rarely match the burden of cancer: the national expenses on cancer in many EU countries have stagnated or decreased, often due to austerity measures and overall poor economic performance, thereby curtailing the budget available for new medicines.

This means that the few resources available must be equitably divided between various modalities (medicines, surgery, radiation oncology, etc) to provide the best value for patients. As a result, decisions on pricing and reimbursement (and ultimately access) are often driven by financial issues more than by considerations regarding the overall value of the overall services brought to patients, therefore increasing the existing inequalities in access to healthcare.

For this reason, ECPC welcomes the introduction of pay-for-outcome schemes that would facilitate the evaluation of the effective value of new medicines. ECPC supports the principle of outcomes-based pricing, which rewards improved outcomes for patients and healthcare systems rather than volume of usage - thereby representing a form of payment for performance. Such schemes must collect patient-reported outcome measures, as well as other clinical, economic and legal/ethical information, in order to provide a comprehensive picture of the real impact of drugs within national healthcare systems. The preconditions to achieve actionable and effective new pricing models are: closer collaboration among EU countries on improving patients' access, better coordinated value assessment, horizon scanning, more consistent investments in health and, at the practical level, a well-functioning and interoperable eHealth infrastructure in each EU country (see Section 4.6). Given the magnitude and the complexity of developing effective models for pay-for-outcome schemes, ECPC strongly believes that the best approach would be via a pan-European collaboration on the economics of cancer. To do this in an efficient manner, ECPC strongly encourages the European Commission, Member States and academia to work together towards the identification of pay-for-outcome models that would be implementable at the national level.

**Reimbursement and pricing mechanisms for innovative medicines
should be aligned with improving health outcomes, including pay-for-outcome models.**

The wider application of outcomes-based pricing will require the integration of an agreed definition of how to measure appropriate outcomes and the establishment of suitable means to collect real-world patient-level data. Pricing should also be flexible over time, reflecting changes in assessed outcomes and cost-effectiveness during the lifetime of the medicine in question.⁵ Research is required to evaluate the link between price and therapeutic value for new cancer medicines in Europe.⁵

Where cancer medicines are used in conjunction with specific diagnostic technologies and biomarkers, and in combination with multiple treatments, there is the potential for outcomes-based contracting for a wider service than for a single medicine alone. Notably, however, the world's largest 'pay for performance' scheme (the UK Quality and Outcomes framework) has not led to significant mortality improvements in cancer or other diseases,⁵³ indicating that further research is required to optimise such approaches.

The pilot initiative by Belgium, Netherlands and Luxembourg to collaborate in shared negotiation on prices for orphan drugs should be observed to see if it results in improved access to treatments. It has been suggested that the Network of Competent Authorities on Pricing and Reimbursement (NACPR) could elaborate pilot projects that could improve access to valuable molecules, including exploring pricing and financing models and optimising data gathering.⁵⁴

EU Members States should co-operate further on innovative approaches to information sharing, transparency, horizon scanning, joint price negotiation and procurement initiatives, with EU support.

Most importantly, it is necessary to routinely and systematically involve patients in pricing decision-making processes. In the scenario described, which requires a very efficient management of scarce resources, patients have little involvement in pricing decision-making. This may reflect a lack of will among authorities and appropriate forums and processes for patient input, together with a lack of knowledge and expertise in this area among patients.

Patients should be routinely involved in pricing decision-making.

FUTURE FINANCE AND DEVELOPMENT MODELS

As mentioned before, pricing and reimbursement models are geared primarily towards meeting financial and economic constraints of EU countries rather than delivering value-based interventions for cancer patients. ECPC clearly recognises the need for healthcare systems to be sustainable. However, expenditure on cancer care (on average, 6% of the total healthcare budget⁵) does not match the burden of disease for the society, cancer being the leading cause of premature death in 17 out of 28 EU Member States (see Section 2.1).

From this perspective, it is necessary to identify innovative approaches to the funding and organisation of drug development that are better integrated with the broader needs for economic sustainability of healthcare systems. Innovative approaches have emerged in recent years, such as the Innovative Medicines Initiative. A longer-term approach to ensuring that the development of cancer treatments is fully orientated toward public health benefit may require consideration of even more radical approaches, such as those recently described by the Belgian Healthcare Knowledge Centre.⁵⁵

The EU and Member States may need to consider fundamentally different financing and development models for cancer medicines.

National early access schemes: case study - Cancer Drug Fund in England

National regulatory approaches to facilitate early access to new cancer medicines include managed access, compassionate use and named-patient schemes in some countries. While these facilitate access to certain medicines to some patients, international variations result in inequities.

The Cancer Drug Fund was established in 2011 to improve access to cancer drugs not routinely funded by the National Health Service in England. By 2016 it was judged unsustainable owing to overspend and lack of evidence of benefit for patients.⁵⁶ The revised Fund is now a managed access scheme linking assessment and reimbursement with the aim to provide fast, fair access to cost-effective cancer medicines. NICE will now undertake an adapted, early pre-marketing appraisal for new cancer medicines. Routine NHS commissioning will be available promptly if the medicine is approved. Alternatively, NICE can issue a temporary conditional approval - triggering funding via the Cancer Drug Fund - if further evidence is needed before a drug is funded routinely.^{57,58} ECPC welcomes the continuation of the Cancer Drugs Fund in its new form. Whether the scheme improves access to existing or future drugs remains to be seen, as two UK cancer charities have cautioned.¹²

3.4 CANCER REGISTRIES

Disease registries are very important for collection of real-world data on disease burden, the effectiveness, safety and cost-effectiveness of innovative treatments, service provision and care quality. Data from disease registries can inform patient care and healthcare planning, as well as providing data for public health policy and research.

Harmonisation in data quality and collection methods is important to support data sharing, as recently underlined by EMA⁵⁹ and researchers.⁶⁰ ECPC was a stakeholder in the cross-border PATient REGistries iNitiaTive (PARENT; www.patientregistries.eu) that supported Member States in developing comparable and interoperable patient registries. This initiative resulted in the publication of Methodological Guidelines and Recommendations for Efficient and Rational Governance of Patient Registries⁶¹ and a list of European patient registries (www.parent-ror.eu/#/registries).

Other barriers to the optimal use of registries include variations between Member States in electronic health record coverage, limits on data sharing, fragmented support, and lack of sustainable funding.⁵⁹ Regarding data protection, ECPC welcomes the European Commission Data Protection Reform Package agreed in April 2016 with amended provisions that support medical research. European-wide collaboration is essential to establish or extend patient registries based on harmonised, high-quality methods of data collection.

The European Network of Cancer Registries (ENCR), hosted by the European Commission's Joint Research Centre in Ispra (Italy), represents a great example of fruitful collaboration between national and regional registries to share methodologies, resources, infrastructure and data. However, without proper funding and sustainability plans, the ENCR would not be able to provide durable solutions to the growing needs and expectations related to cancer registries. ECPC therefore recommends the European Commission to strengthen Member States' collaboration on cancer registries by exploring possible long-term solutions to further centralise and harmonise the collection of data on cancer across all EU countries.

The European Commission should promote the harmonisation of national cancer registries, and propose plans for the centralisation of the registries at the European level.

4. BEYOND MEDICINES: PROMOTING WIDER INNOVATION

Many forms of innovation can offer benefits for patients, healthcare systems and societies. Digital health technologies, service models, educational approaches, as well as non-drug treatments and diagnostic approaches, are crucial in delivering equitable and sustainable access to innovative technologies and procedures in oncology. However, these benefits will not be realised unless health systems are enabled to adopt them. As Sir Hugh Taylor, Chair of the UK Government Accelerated Access Review, has stated: '*We have to energise the health system so that it is receptive to innovation and sees and uses new technologies as the best lever for delivering improved care with greater efficiency.*'⁶² The benefits of improved efficiency of cancer services can be seen from the fact that, while spending on cancer medicines has increased in recent years, total cancer expenditure has remained stable owing to reductions in spending on inpatient hospital care.⁵

Clear reimbursement pathways are needed to ensure patients have access to all forms of value-adding innovation.⁶² In England, a new Innovation and Technology tariff aims to accelerate and expand the adoption of a range of innovative medical technologies (e.g. devices, monitors and apps) by providing a specific national reimbursement route.⁶³ This will reportedly guarantee automatic reimbursement when an approved innovation is used. Local providers will not need to negotiate prices, while instead the health service will negotiate national 'bulk buy' discounts. This system is supported by an Innovation Accelerator Programme intended to make evidenced innovations more widely available to patients.⁶⁴

Cancer patients believe in innovation and in research - consulting further with them would help ensure that innovators are looking at the aspects of conditions that patients feel most strongly about. Patients should be integrally involved in priority setting, decision-making and commissioning, conduct, evaluation and dissemination of innovation.

EU Member States should co-operate, with EU support, on means to optimally assess, reimburse and scale up innovative health technologies other than medicines, according to a patient-centred, evidence-based approach.

Patients should be supported to play a greater role at all stages of research into all innovative approaches to cancer care.

4.1 IMPROVING ACCESS TO INNOVATIVE DIAGNOSTICS

Early detection of cancer is desirable, as this allows earlier treatment and often results in longer survival and improved QoL. All cancer patients should have access to early diagnosis followed by high-quality treatment. Current diagnostic tools commonly used include biopsies, imaging tests (such as X-rays, positron emission tomography (PET)/computed tomography (CT) scans, magnetic resonance imaging (MRI) and ultrasound) and endoscopies. There is a need for innovative diagnostic tests that are sensitive, fast, inexpensive, non-invasive and have a low false positive rate (i.e. high specificity).

Various innovative diagnostic tools have been developed in recent years, some of which can provide great value to patients and healthcare systems.

- Imaging technologies, such as capsule endoscopy, optical coherence tomography and positron emission mammography, have the potential to improve the detection of early stage tumours.⁶⁵
- Liquid biopsy is a new diagnostic method that uses urine, blood or saliva rather than a tissue sample to obtain information about the cancerous cells found in a tumour. For some cancers, liquid biopsy is becoming a compliment to tissue biopsy, with the potential to improve testing and disease management.
- Cancer biomarkers are proteins or other biological substances that give information about the presence and activity of cancer in the body. They can be used to diagnose early stage cancers and to ensure that the most appropriate treatments are prescribed.

ECPC places particular focus on biomarkers, given the crucial role that they play in the delivery and efficacy of personalised medicine treatments. In 2016, the ECPC survey on biomarkers collected information from more than 150 respondents regarding awareness, access and reimbursement of biomarkers in Europe. The results underlined the need to work towards three main objectives:

- **Increase biomarker literacy:** Health authorities, physicians and patient groups need an improved awareness regarding genetic testing. Communication focused upon access to testing and how it can aid in patient care provides an important opportunity to engage patients in managing their health as active partners and to inform them about breakthrough developments in medical technologies.
- **Improve access:** The development of biomarker-based diagnostics can facilitate faster diagnosis and treatment. For this to happen, these tests need to be integrated in the clinical setting and to be affordable and available to all patients.
- **Adapting the regulatory framework:** Regulatory and reimbursement processes must be adapted to the specificities of new biomarker technologies. Hospitals and other clinical settings must also adapt to respond to associated challenges such as quality and assurance of the diagnosis and data privacy. In addition, a better integration of diagnostic regulations into medicines regulation frameworks could improve the reimbursement and access of biomarker tests.

The factors driving acceptance and clinical use of new diagnostic technologies are complex. Regulatory approval is crucial, but without national reimbursement, these technologies are unlikely to be widely used. Data from clinical trials and real-world evidence should be used to improve the sensitivity and specificity of new diagnostic methods and biomarkers, as well as to better understand the value of these tests to cancer patients.^{66,67}

National governments should promote the uptake of innovative diagnostic technologies by implementing European regulatory frameworks to favour their reimbursement, when supported by consistent clinical data.

The European Commission and the European Council should promote patients and physicians' literacy on biomarkers and other innovative diagnostic tools available.

4.2 IMPROVING ACCESS TO INNOVATIVE RADIATION ONCOLOGY

Across Europe, around half of all patients diagnosed with cancer would benefit from radiation oncology at some point during their treatment,¹⁸ making radiotherapy a crucial pillar of cancer treatment.

Innovative radiotherapy technologies include new methods that target tumours with increasing precision, allowing high doses to be delivered more safely. These include stereotactic ablative radiotherapy, implantable forms of radiotherapy (image-guided brachytherapy), and molecular radiotherapy using radiopharmaceuticals.

However, access to quality radiotherapy treatment remains an issue in most European countries. Around one in four of these patients do not receive the radiation oncology treatment they need^{18,68} and significant variations exist across Europe in patients' access to modern services.^{16,18} The European Society for Radiotherapy and Oncology (ESTRO) has estimated that the need for radiotherapy in Europe is expected to increase on average by 16% from 2012 to 2025, with considerable variation between countries reflecting existing disparities.⁴

According to this analysis, the key innovation needed in radiation oncology pertains to investment models that can provide access to high-quality radiotherapy care. Investment in radiation oncology services is essential and should take a long-term perspective. Globally, investment in radiation oncology services not only enables the treatment of large numbers of patients to save lives, but also brings a positive economic impact with the benefits of upfront investment being realised over 10-15 years.⁶⁹ Investing in machines and infrastructure alone is not sufficient: staffing levels of appropriately trained healthcare professionals must also be increased.⁶⁹

Every cancer patient in Europe who would benefit from radiation oncology treatment should have access to it as part of an individualised, multidisciplinary approach.

To help overcome disparities in access, radiation oncology should be positioned within care models - and reimbursed - according to a patient-centred, evidence-based approach.

Investment is necessary both in radiotherapy equipment and the training of radiation oncology healthcare professionals.

4.3 IMPROVING ACCESS TO INNOVATIVE SURGERY

CONSOLIDATING THE FUTURE OF EUROPEAN SURGEONS

Surgery is one of the most effective treatment options for many solid tumours, and is best conducted by well-trained surgeons in the early stages of disease. By 2030, it is estimated that there will be 21.6 million new cancer cases worldwide, of which 17.3 million (80%) will need surgery.⁷⁰ The failure to provide adequate cancer surgery could lead to a loss of US\$6.2 trillion globally by 2030.⁷¹ The main factor impeding access to safe and affordable cancer surgery is the scarcity of surgeons who are trained and educated in the management of patients with different cancer diagnoses. Disparities in the availability of surgeons exist across Europe, with Norway and the Netherlands having more surgeons per inhabitant compared to Turkey, Tajikistan, and Kyrgyzstan.⁷²

The ability to develop a sustainably adequate surgical oncology workforce depends on the presence of robust educational systems that promote training in all oncologic domains and helps to maintain competency for those in clinical practice. The training of surgical oncologists worldwide is extremely variable; cancer surgery will improve only if training curricula are harmonised and a scaffold for common requirements is provided. However, even if a European Board of Surgical Oncology qualifying exam were to exist, at present such achievement in isolation would not facilitate the recruitment of new surgeons specifically devoted to cancer treatment. This is because the competency dilemma is accompanied by a shift away from surgery as a career choice by medical students burdened with university loans and who desire less stressful lifestyles. This is particularly true in low and medium income countries.

New approaches to teaching and training next-generation surgical oncologists must be quickly implemented into educational programmes throughout Europe.

National cancer control plans must include the strengthening of surgical systems through investment in public sector infrastructure, education and training.

Low-resource countries should be encouraged to partner with other countries that offer surgical oncology fellowships to improve the training of oncologic surgeons, to help standardise high-quality treatment plans.

ACCESS TO NEW SURGICAL PROCEDURES

Cancer surgery has improved over time, with the introduction of innovative instrumentation and techniques such as robotic surgery and implantable chemotherapy devices. Another example is laparoscopic surgery, an innovative minimally-invasive technique that has been effectively implemented in many European countries. This technique reduces post-operative pain and reduces the duration of time in hospital.

There are currently 227 different surgical procedures available to treat cancers, and novel techniques can be technically highly complex. This variety of options increases decision-making dilemmas for surgeons and patients, who question which procedures to accept. Innovative surgery should increase longevity, improve QoL, ensure productivity or offer long-term benefits.⁷³

New surgical approaches should be adequately tested and validated, properly implemented into educational programmes together with appropriate safety precautions.

In the development of innovative surgery, the focus should be on longevity, long-term survival, quality of life and full integration with multidisciplinary treatment.

4.4 IMPROVING THE ORGANISATION OF CARE AND PATIENT PATHWAYS

Clinical experience with some cancers is often limited among many primary care health professionals and centres. Cancer patient pathways provide guidance to primary health professionals and hospitals by outlining well-defined sequences concerning clinical suspicion of cancer, diagnosis, treatment and care. Patient pathways are designed to optimize logistics, reduce the time to diagnosis and treatment, and improve patient outcomes.

Within Europe, standardised cancer patient pathways have been introduced in Catalonia and Madrid (Spain),^{74,75} Denmark,⁷⁶ Sweden⁷⁷ and the UK.⁷⁸ In Denmark, cancer patients referred to a standardised patient pathway had a shorter diagnosis interval than historical controls.⁷⁶ However, most cancer patients were not initially referred to a cancer patient pathway. Satisfaction with care quality has also increased among both patients and staff after the introduction of cancer patient pathways.⁷⁹

ECPC is working with the OECI to improve patient care pathways. Both organisations are collecting best practices in order to produce recommendations to ensure that European cancer institutes implement innovative and patient-centric cancer patient pathways. OECI has also introduced an accreditation program that aims to improve and formally organise cancer care pathways.⁸⁰

The performance of standardised cancer patient pathways should be carefully monitored, and successful strategies should be implemented into national cancer plans.

4.5 DISINVESTMENT

Disinvestment⁸¹⁻⁸⁵ refers to *'resource allocation decisions based on withdrawing funding from no or low added-value health interventions, freeing up these resources for reinvestment in other health technologies that meet the criteria of safe and cost-effective care.'*⁸³

Disinvestment is therefore the practice of continuously re-evaluating healthcare practices to identify which are delivering sufficient value to patients at the best possible cost-effectiveness ratio. The identification of underperforming healthcare services and pathways providing low-value care can allow resources to be re-directed to better (possibly new) solutions. From the patients' perspective, the main objective of disinvestment strategies should be to save and redirect resources to ensure patients' access to meaningful and affordable innovation.

Any effort at national and European level to better assess the economic, clinical, societal and ethical/legal value of existing cancer care services should take into account the potential effect of disinvestment policies, to ensure that the growing burden of disease is met with sufficient resources. The European Commission's Joint Action on Cancer Control (CanCon) has dedicated a specific policy paper on the concept of re-allocation of resources to enhance value in cancer care, which will be presented during the final conference of the Joint Action in Malta. As one of the contributors to the paper, ECPC provided input on the patients' expectations regarding disinvestment policies.

Patient representatives should be involved in decision-making at the national, regional or local levels at which disinvestment strategies are implemented. The European Commission has demonstrated how decision-makers can embed patients in consultative bodies (e.g. Expert Group on Cancer Control and the CanCon Joint Action). Similar models should be used to include local cancer patients' organisations in the decision-making processes within countries.

It is therefore crucial to identify local expert patients and patients' advocates able to provide meaningful input into certain parts of the decision-making process on disinvestment.

Every effort should be made to ensure that patients' voices are heard throughout that these processes are designed so as to allow patients to contribute to the identification and removal of low value and inappropriate care.

4.6 ENABLING THE EHEALTH AND MHEALTH EVOLUTION

The wider use of information communication technologies (ICT) in health, or 'eHealth': has the potential to deliver more personalised healthcare that is more targeted, effective and efficient for the benefit of the public, patients and healthcare professionals.⁸⁶ eHealth tools can improve our healthcare systems, facilitating the collection and elaboration of patients' data for a variety of purposes. eHealth and mobile (m)Health therefore represent evolutions of the current delivery of care systems, whereby ICT technologies are applied to existing care pathways.

A solid eHealth infrastructure is the necessary precondition to achieve several of the recommendations set out by ECPC in this paper, for example:

- Pay-for-outcome models need robust real-world evidence collecting systems, based on harmonised, interoperable eHealth tools and standards
- All initiatives aimed at raising patients' and physicians' awareness need to take into consideration eHealth and ICT literacy
- Clinical trials and fast-track market approvals rely on more efficient eHealth systems able to gather and organise large amounts of data
- Disease registries need reliable eHealth infrastructure to collect and store patients' data.

It is therefore easy to understand why eHealth and mHealth remain key pillars for the development of more equitable and better-performing cancer care pathways.

ECPC strongly believes that implementing a solid European eHealth infrastructure and boosting the development of mHealth tools can be beneficial on several levels:

- **Efficiency:** by streamlining the pathways of care, and by better sharing patients' data across all healthcare professionals involved in the care process, eHealth can provide better services to cancer patients and ultimately benefit their survival and QoL
- **Cost-effectiveness:** eHealth tools can help drive down costs, allowing a better allocation of scarce resources⁸⁷
- **Patient empowerment:** eHealth and mHealth are founded on the improved sharing of patients' information. A comprehensive and unified patients' dataset can be extremely empowering for patients, providing they are true partners in the process of developing such data and retain full ownership and control over them
- **Evaluation of healthcare systems:** eHealth infrastructures are at the centre of all 'pay for outcome' models, by which healthcare providers, medical devices industry and pharmaceutical companies are rewarded not for the products they provide, but for the outcomes their services deliver in the target population (see Section 3.3). Without a solid eHealth infrastructure we will not be able to change our unsustainable payment methods from product-based to service-based systems.

At the same time, ECPC is aware of several obstacles that must be overcome to unlock the true potential of eHealth and mHealth.

ENABLING E HEALTH: INTEROPERABILITY, MORE EVIDENCE, PAYMENT MODELS

The primary obstacle for the implementation of solid eHealth services is interoperability. ECPC fully endorses the European Commission eHealth Action Plan, which states that *'Interoperability of eHealth solutions and of data exchange is the precondition for better coordination and integration across the entire chain of healthcare delivery and health data exchange, while unlocking the EU eHealth single market.'*⁸⁶

In our view, it is necessary to develop and implement mandatory and specific eHealth standards at EU and national level to ensure that all eHealth solutions are produced in a fully integrated environment.

The European Commission should promote, develop and implement eHealth specific standards to harmonise the deployment of innovative eHealth solutions.

While interoperability is a precondition for any success using eHealth, the public health community is still uncertain about the economic benefits of eHealth solutions. ECPC is aware of several studies and pilots showing how eHealth solutions can increase the efficiency of healthcare services and cut costs. However, more evidence is necessary to generate trust in these new technologies and promote the political momentum towards greater and better investments in eHealth. ECPC calls on all Member States to launch pilot projects at national level, following the example of European Commission-funded research projects, to better analyse the cost-effectiveness of eHealth tools.

Member States should promote and implement research projects and pilots to gather evidence on the cost-effectiveness of eHealth tools.

Finally, it is important to state that eHealth will be unsuccessful if we simply transpose processes within care pathways from analogue to digital. If we merely introduce electronic patients' records, telemedicine and other instruments without re-thinking to the core the care pathways and the existing payment models, we will simply retain outdated pathways with expensive ICT tools. For this reason, ECPC strongly calls on the European Commission and Member States to analyse how to develop innovative payment models that would allow for the full integration of eHealth tools.

Member States, in close collaboration with the European Commission, should expand innovative payment models to seamlessly implement innovative eHealth solutions within new care pathways.

PLACING PATIENTS AT THE CENTRE: MHEALTH

mHealth is the field of eHealth covering medical and public health practice supported by mobile devices. mHealth technologies have the potential to facilitate innovative models of integrated, multi-professional care, empowering patients and improving both their experience of cancer care (e.g. through information and engagement with health services) and the associated outcomes. Realising the benefit of mHealth will require its usage to be expanded and embedded within routine processes and pathways at all stages of care, as compared with their limited application at present.⁸⁸

In previous years, ECPC closely followed the development of two crucial pieces of legislation to regulate the creation, entry into market and monitoring of mHealth apps: the General Data Protection Regulation and the Medical Devices and In Vitro Diagnostics Regulations.^{89,90} Both legislations are due to enter into force between 2016 and 2019, substantially modifying the way mHealth apps can collect, process and share patients' data.

Notwithstanding the crucial changes in the regulatory framework, the mHealth market seems not to have halted: mHealth represent one of the fastest growing app markets on both iOS and Android platforms. At the same time the wide 'grey zone' between EU and national legislations needs to be targeted by precise initiatives by the European Commission and national and European stakeholders to ensure that patients' safety and privacy rights are preserved while allowing them to benefit from the advantages of mHealth.

In particular, ECPC believes that there are two specific types of issues in the development of effective mHealth apps, relating to:

- Safety of patients' data, i.e. data protection
- Quality and efficacy of apps.

Data protection is important and is achievable with simple safeguards, and privacy concerns should not obstruct valuable innovation in mHealth. In 2016, European industries involved in mHealth produced a Code of Conduct with the objective to self-regulate the use of mHealth apps.⁹¹ ECPC contributed to the drafting of the Code by submitting specific comments.⁹² Overall, ECPC supports the purpose of the Code, and believes the draft generally complies with the needs of cancer patients and their carers in respect to privacy. The Code is a much-needed tool to increase the trust of users in apps that have the potential to enhance their access to quality healthcare and to increase QoL. However, we are concerned regarding the implementation of the Code, in particular the governance and adherence structures. The Code risks not delivering on its promises without a strong, reliable, centralised governing structure. Ultimately, if the Code is not implemented via a solid governance system, it may not protect users of mHealth apps as it is intended to do. The laudable efforts of the Code Writing Group and the supporting stakeholders must be met with equal efforts to establish a reliable governing structure to ensure that the burden of the risk does not lay on the end user.

The European Commission and all stakeholders involved in the drafting of the Code of Conduct on privacy for mobile health applications must ensure a solid implementation of the Code.

Patient consent should be gained using a short, simple statement without legal jargon, such as those provided in the European Commission's Code of Conduct on privacy in mHealth apps.

The European Commission has launched a Working Group to develop guidelines for assessing the validity and reliability of the data that health apps collect and process.⁹³ ECPC and 19 other members representing civil society, research and industry organisations were selected to participate in the working group. We are glad that the European Commission recognised the need to better regulate this area. The guidelines are essential to ensure that mobile cancer apps are scientifically credible and user-friendly for patients and carers. To this end, ECPC shared several key recommendations during the drafting of the Guidelines, which are expected to be published in 2017.

Apps should be patient-centred by design and by default, hence ECPC favours the involvement of patients from the early stage of development onwards.

Apps should provide correct and reliable information from cited and reputable sources. Collaboration with medical societies may be helpful to check the validity of the sources.

Options should exist for app developers (especially in academia) to collect anonymised data for research purposes.

National-level pathways for the assessment and reimbursement of digital health innovations require clarification and support.

5. CONCLUSIONS

Innovative healthcare technologies, strategies and services offer the potential to improve the lives of many people living with cancer. Ensuring that effective innovations are accessible and affordable to all patients is a challenge facing all cancer stakeholders.

The successful development and implementation of new cancer care modalities stems from putting the needs of patients at the centre of the innovation process. Patients are the ultimate beneficiaries and users of cancer diagnosis, treatment, and care. They have unique knowledge, perspectives and experiences that improves and encourages innovation in oncology. Optimal innovation can only be obtained by understanding the diverse needs and preferences of cancer patients, and integrating patient-centred approaches into the regulatory and healthcare system.

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