II LUCE REPORT ON LUNG CANCER

DISPARITIES IN DIAGNOSIS, CARE AND TREATMENT ACCESS

Lung Cancer Europe

LuCE REPORT ON LUNG CANCER

Disparities in diagnosis, care and treatment access

NOVEMBER 2017

After the 1st LuCE Report in 2016, in which we highlighted the main challenges in lung cancer in Europe from the patient perspective, we launch this 2nd Report to deepen our research on one of our main worries: disparities on access across Europe.

Lung Cancer Europe (LuCE) represents lung cancer patients and caregivers, no matter the place they live, and we advocate for the best support as possible for all of them. But, as this report evidences, disparities in diagnosis, treatment and care access exist between different European countries, so we need solutions. We encourage our collaborators in the fields of policy, science, research and civil society to read this report and we call on them to work together.

Many faces, one voice.

Access here to the 1st LuCE Report:
www.lungcancereurope.eu/wp-content/uploads/2016/11/LuCE-Report-final.pdf

Raising awareness among policymakers about disparities in the accessibility to diagnosis and treatment

Lung cancer patients have increasingly higher expectations in regard to treatments. Thanks to the advances made in lung cancer therapy and care, and to the many clinical studies in progress, we now have more medications available and there is more information about how to fight against lung cancer.

I was diagnosed with lung cancer 15 years ago and, like many other thousands of patients, I am really grateful for these great progresses made in the treatment of this disease. I still remember how, at that time, surgery was the best treatment for around 20% of patients and chemotherapy and radiation were the best for the remaining 80%. There was little research on the treatment of lung cancer.

Now we have new treatments that either treat lung cancer patients or give us many months, even years, of good quality of life. But we will not be able to accomplish these objectives if these innovative treatments are not available for patients. Access is one of our main challenges today.

Access to molecular testing and new medicines differs in individual countries across Europe, even within the same country. There are several factors that contribute to treatment access barriers and inequalities across Europe. The high cost of some of these treatments has produced differences in the ability of healthcare systems to reimburse all treatment options. In addition, new treatments are often given alongside conventional treatment, increasing the overall cost of treating patients.

Time is another inequitable factor. Delays in patient access to new treatments happen across Europe, and this time depends on each country and the setting where the drugs are used. The EU directive on pricing and reimbursement specifies a 180-day limit post company submission for price, but compliance with this deadline is extremely variable.

This 2nd LuCE Report is especially focused on access to diagnosis, treatment and care, because we maintain that all lung cancer patients must receive the best care and treatment available at the right time. As we highlighted in our 1st LuCE Report, lung cancer is the main cause of cancer deaths in the EU, being responsible for nearly one in five cancer deaths worldwide. We therefore need solutions to offer care and support as soon as possible, especially if we consider that most of the lung cancer patients are diagnosed in an advanced stage.

Having successfully fought off lung cancer, I am passionate about persuading policymakers and other stakeholders to take action and ensure that lung cancer patients gain timely diagnosis and access to the latest treatments, and give them the best chance of survival and a good quality of life. To achieve this, policymakers need to be aware and informed about our priorities as patients in order to make the right decisions. This report will play a crucial role in informing them and we urge all supporting organisations in every country to use this report in advocating for change in national lung cancer healthcare.

Regine Deniel Ihlen

Patient advocate and Treasurer of Lung Cancer Europe (LuCE)

Table of contents

1. ABOUT THIS REPORT

The landscape of lung cancer treatment is rapidly evolving. Over the last decade, great progress has been made in expanding the knowledge and understanding of molecular drivers of cancer in order to develop a new era of lung cancer treatments.1 The introduction of immune therapies to treat lung cancer is also changing the face of the disease, extending both durable remissions and prolonging survival[1].

-THIS IS THE 2ND STAGE OF A PROJECT THAT AIMS TO MAKE HEALTH STAKEHOLDERS AWARE ABOUT CHALLENGES REGARDING LUNG CANCER IN EUROPE-

However, we believe significant barriers in accessing these treatments still exist, or are even increasing in some cases, in the form of high regulatory hurdles and access for new medicines and diagnosis at a late stage, with five-year survival rates remaining low in Europe and lack of a specialised multi-disciplinary structures to ensure adequate lung cancer patient care. The purpose of this report is to review the different challenges around lung cancer, with specific focus on the existing barriers and inequalities in access to diagnosis and treatment for patients in Europe.

Our report constitutes the second stage of this project, following the 1st LuCE report launched in 2016 at the European Parliament, along with our calls to action. The 2016 report provided a general overview of lung cancer incidence in Europe and the challenges faced in selected countries. This report builds on the one from last year, with a focus on how to help different stakeholders contribute to better access to early diagnosis, molecular testing and innovative treatment for lung cancer patients.

METHODOLOGY

This report provides an analysis and a description of the current challenges in access to early diagnosis, molecular testing and innovative treatment for lung cancer patients in Europe This data has been obtained from different sources of information from May to September 2017.

Desktop research of primary and secondary policy sources was conducted mainly in English but additionally in Spanish, French, Italian, German, Dutch, Swedish, Danish and Norwegian (see *References and Sources*)

Three qualitative interviews (one oncologist and two national patient group representatives)

Two quantitative and qualitative online surveys on access to lung cancer medicines for healthcare professionals from 16 countries* (54 responses: 40 from academic hospitals, 12 from non-academic hospitals and two from private practice) and lung cancer advocates (eight responses, members of LuCE)

An additional survey of pharmaceutical companies** on access to lung cancer treatments and diagnostic tests in 18 countries***

Final data about access to diagnosis and drugs was reviewed by LuCE members

* England, France, Germany, Spain, Italy, Netherlands, Romania, Poland, Norway, Ireland, Israel, Switzerland, Denmark, Austria, Greece and Serbia
** AstraZeneca, BMS, Boehringer Ingelheim, Lilly, Merck, Pfizer and Roche
*** UK, France, Italy, Finland, Germany, Spain, Portugal, Netherlands, Romania, Poland, Denmark, Sweden, Norway, Ireland, Israel, Slovenia, Switzerland and Turkey

2. ACCESS TO DIAGNOSIS, CARE AND TREATMENT

Diagnostic tools and therapies are more effective and safer nowadays. In recent years this leds to the possibility to ensure a better quality of life for lung cancer patients.[2] New and advanced treatment options such as targeted therapies and immunotherapies are bringing about new opportunities in lung cancer care.

For example, targeted therapies for non-small-cell lung cancer (NSCLC), such as epidermal growth factor treatments (EGF) gefitinib, erlotinib, and afatinib, and the anaplastic lymphoma kinase (ALK) inhibitors crizotinib, alectinib and ceritinib, represent important innovations in treatment over the last decade.[2] By targeting the main pathways of NSCLC pathophysiology, these new drugs have significantly improved survival rates and quality of life in a highly selected subgroup of patients. In addition, treatments used a decade ago still remain crucial and effective options for many patients.[1]

However, in order for these treatments to work effectively and efficiently, they need to be available and reimbursed, and diagnostic tools must be available for patients.

Molecular diagnostics offer important benefits to patients, but are not necessarily and equally available. Identification of a specific genetic alterations in patients with NSCLC helps clinicians to select the best treatment option. In the case of NSCLC, certain genetic alterations can be used to identify patients who might be sensitive, or resistant to, a particular cancer therapy.

Despite their promise, unequal access across countries, and sometimes even within individual countries, remain.[3] Although most of these tests will be available in all these countries, there are no formal avenues for reimbursement of diagnostic tests. For instance, in Spain, although there is no formal process for reimbursement of diagnostic tests, hospital centres pay for these tests, if considered necessary, by clinicians.

To know more about the accessibility of molecular tests across Europe, we asked LuCE members (patient advocates) to complete a short questionnaire about the administrative status of four different biomarkers diagnoses: ALK, EGFR, PD-L1 and ROS1.

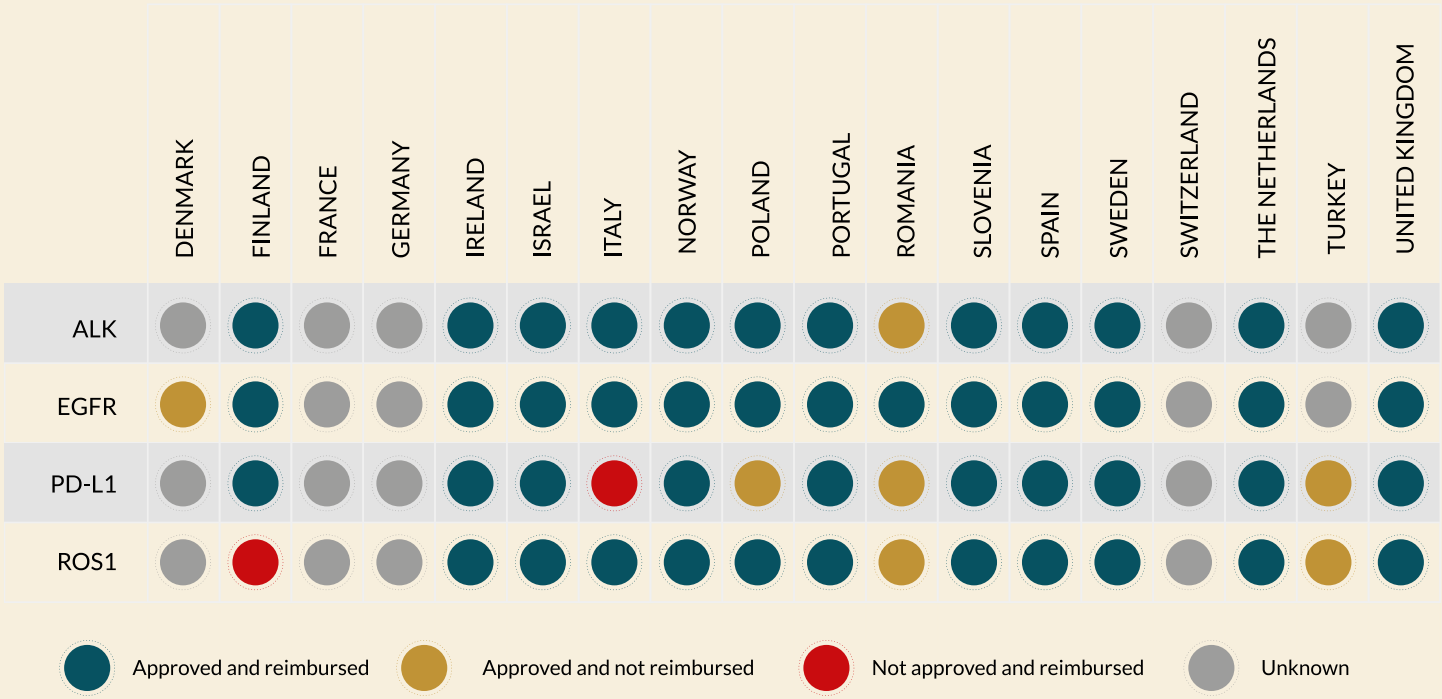
To consider: Updates about approval and reimbursement may occur since the data was collected. Also, it must be highlighted that even when a test is considered approved and reimbursed, some barriers may happen in some European countries because of regional differences or other different reasons.

DIAGNOSIS

UNEQUAL ACCESS TO MOLECULAR DIAGNOSTICS ACROSS, AND SOMETIMES WITHIN, EUROPEAN COUNTRIES

Availability of lung cancer molecular tests

(Country selection criteria: LuCE member organisations working - or with influence - in these countries)



With reimbursement, in this table, we refer that they are registered and available for the majority of patients through universal healthcare coverage, i.e., through public funding or private insurance

LUNG CANCER DRUGS
HIGH DISPARITIES AMONG EUROPEAN COUNTRIES. ACCESS IS A RELEVANT CHALLENGE IN EASTERN EUROPE

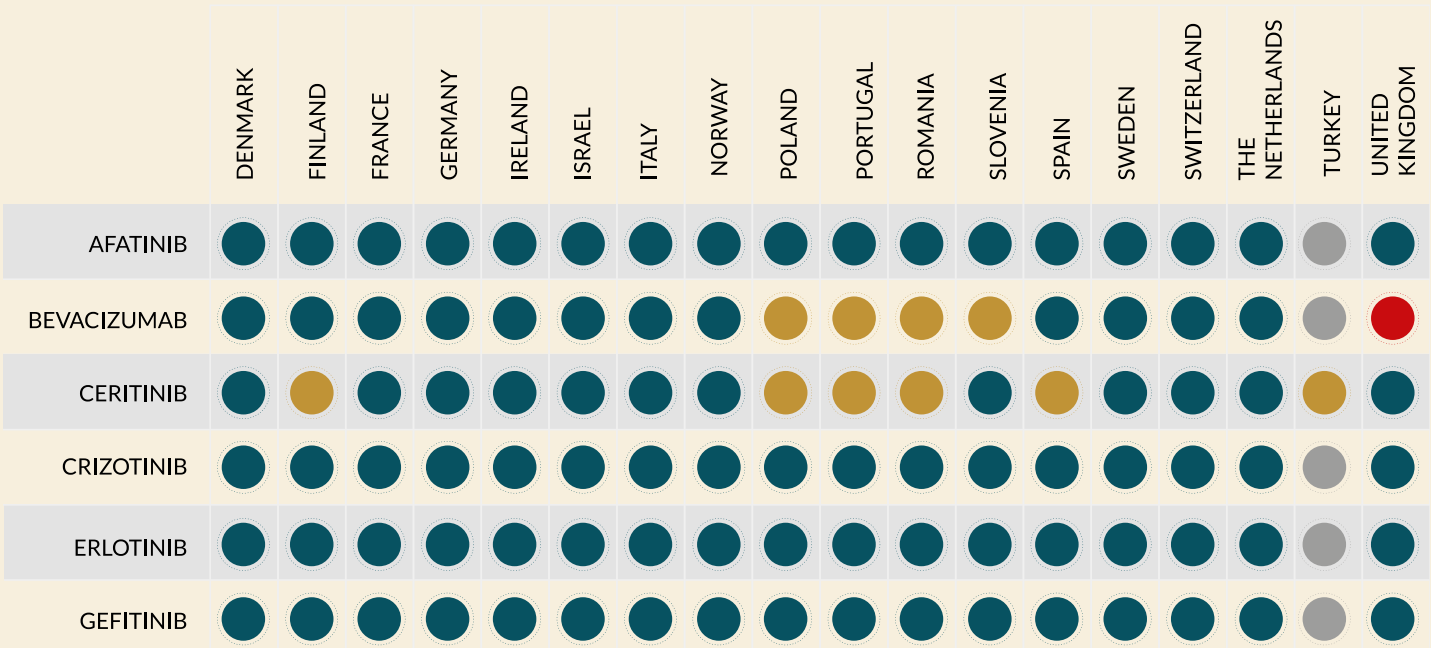
There is strong evidence that access to cancer treatments remains inequitable across Europe. For instance, recent research about some oncology drugs approved by the EMA for the treatment of six cancers (lung cancer is one of them) between 2006 and 2016 showed that 26% of published decisions resulted in complete or partial restriction, and the level of restrictions is different depending on the country (Germany 0%, Portugal 4%, Scotland 63%).[4]

Barriers to access to cancer drugs are unacceptable, especially when they affect patients with incurable diseases. If we promote access and get more efficient health services and research, we would be able to give hope and opportunities to lung cancer patients.

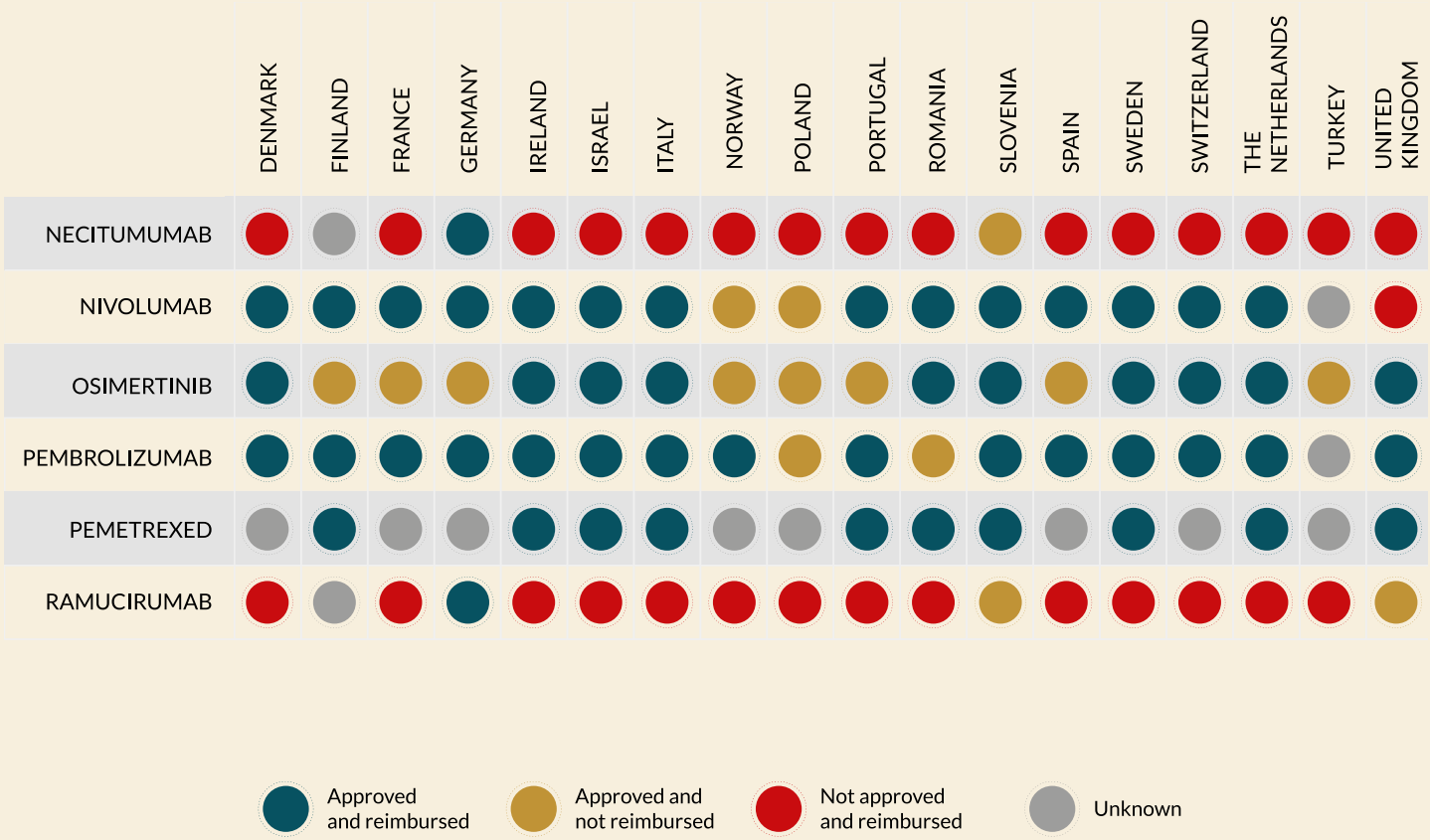
The current scenario is very complex and dynamic, with many new drugs and studies ongoing, and a huge diversity of national regulatory and reimbursement processes (even regional, in some places). So we asked patient advocates, health care professionals and pharmaceutical companies to get an insight into the access situation of lung cancer drugs across different European countries. These countries have been selected because there is a LuCE member organisation working - or with influence - in these countries.

To consider: Updates about approval and reimbursement may occur since the data was collected. Also, we collected data shown some differences in the answers received by HCP, advocates and pharmaceutical companies about the administrative status of some drugs in specific countries. In the last review, LuCE members discussed these controversies with their scientific boards to review these data again and select the best answer. These differences and controversies remark the importance of raising awareness about access to treatments among the HCPs, advocates and pharmaceutical companies. Another limitation to consider is that even when a drug is considered approved and reimbursed, some barriers in drug uptake may happen because of regional differences or because it can be available to a specific and limited group or patients.

Availability of lung cancer drugs



With reimbursement, in this table, we refer to medicines that are registered and available for the majority of patients through universal healthcare coverage i.e. through public funding or private insurance. However, special conditions apply to access to specific cancer treatment across countries. For instance, Crizotinib is reimbursed in the UK via the e NHS Cancer Drug Fund and in Poland via special insurance


DENMARK
FINLAND
FRANCE
GERMANY
IRELAND
ISRAEL
ITALY
NORWAY
POLAND
PORTUGAL
ROMANIA
SLOVENIA
SPAIN
SWEDEN
SWITZERLAND
THE NETHERLANDS
TURKEY
UNITED KINGDOM
NECITUMUMAB
NIVOLUMAB
OSIMERTINIB
PEMBROLIZUMAB
PEMETREXED
RAMUCIRUMAB
Approved and reimbursed
Approved and not reimbursed
Not approved and reimbursed
Unknown

Disparities in access to lung cancer treatments have already been highlighted by the European Society of Medical Oncology, in 2016. The ESMO European Consortium Study on the availability, out-of-pocket costs and accessibility of antineoplastic medicines in Europe collected data about the availability of EGFR-mutated non-small-cell lung cancer and it showed high disparities in accessibility between countries.[5] Data showed that while in Western Europe these medications are usually available and fully subsidized, in Eastern Europe treatments are not reimbursed, or available only at the full cost to patients (see tables on the next page).

In Poland, for example, a patient paying for a treatment out-of-pocket may still face problems when receiving the medication, because if it is not reimbursed, the procedure is not either. The consequence is that even when a patient pays a lot of money, he/she cannot get the medication because hospitals refuse to undertake the procedure.

LUNG CANCER. Availability (2016)				
Country:	Erlotinib	Gefitinib	Afatinib	Crizotinib
Austria				
Belgium				
Cyprus				
Denmark				
Finland				
France				
Germany				
Greece				
Holland				
Iceland				
Ireland				
Israel				
Italy				
Luxembourg				
Norway				
Portugal				
Spain				
Sweden				
Switzerland				
Turkey				
United Kingdom				

Always
Usually
Half the time
Occasionally
Never
Not available
Missing data

From: ESMO European Consortium Study on the availability, out-of-pocket costs and accessibility of antineoplastic medicines in Europe. Ann Oncol. 2016;27(8):1423-1443.

LUNG CANCER. Availability (2016)				
Country:	Erlotinib	Gefitinib	Afatinib	Crizotinib
Albania				
Armenia				
Belarus				
Bosnia and Herzegovina				
Bulgaria				
Croatia				
Czech Republic				
Estonia				
Georgia				
Hungary				
Kazakhstan				
Kosovo, Republic of				
Kyrgyzstan				
Latvia				
Lithuania				
Macedonia				
Malta				
Montenegro				
Poland				
Romania				
Russian Federation				
Serbia				
Slovenia				
Slovakia				
Turkmenistan				
Ukraine				
Uzbekistan				

CLINICAL TRIALS
MOST TRIALS FOR LUNG CANCER PATIENTS ARE RUN IN WESTERN EUROPE

Clinical trials are an opportunity for lung cancer patients to receive cutting-edge treatments. They can benefit from receiving drugs in the late stages of testing that are not yet approved in their countries and, therefore, they would not otherwise have access to.

It is therefore understandable that better access to clinical trials is a priority for many of them, but some issues may influence the possibility to be involved in these studies. For instance, the level of knowledge about the ongoing clinical trials or the socioeconomic status of a patient can play a role, as well as the place (hospital or country) where the patient is being treated.

Clinical trials are usually run in a few specific countries. According to the website www.clinicaltrials.gov, most of them are developed in Western Europe: France, United Kingdom, Spain, Italy and Germany. This situation causes enrollment disparities, therefore, not all European lung cancer patients have the same opportunities to get involved in a clinical trial.

The European Clinical Trial Regulation (No. 536/2014) ensures that the rules for conducting clinical trials are identical throughout the EU, and facilitates access by centralized approval processes. This regulation aims to standardise and harmonise clinical trial amongst member states. However, according to our survey, 42% of the health care professionals rate the access to new drugs in clinical trials as poor (35%) or very poor (7.5%). Therefore, there is great room for improvement. New regulations shall foster patient recruitment and promote cross border access to clinical trials.

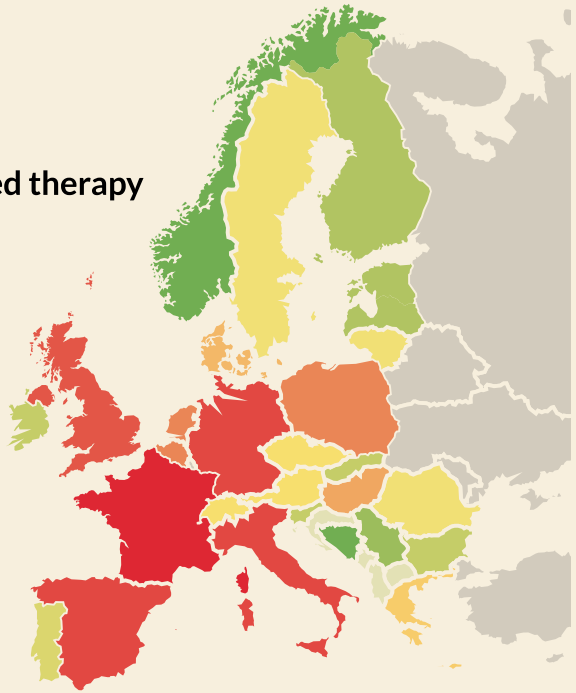
> The right to expect research to be conducted on their particular cancer type and to be offered access to clinical studies where available and relevant to their condition
>
> -Article 2.8, European Cancer Patient´s Bill of Rights-

Lung cancer clinical trials in Europe

COLOR INDICATE THE NUMBER OF STUDIES
WITH LOCATIONS IN THAT REGION

LEAST MOST

Targeted therapy



Immunotherapy

Source: www.clinicaltrials.gov (accessed September, 2017)

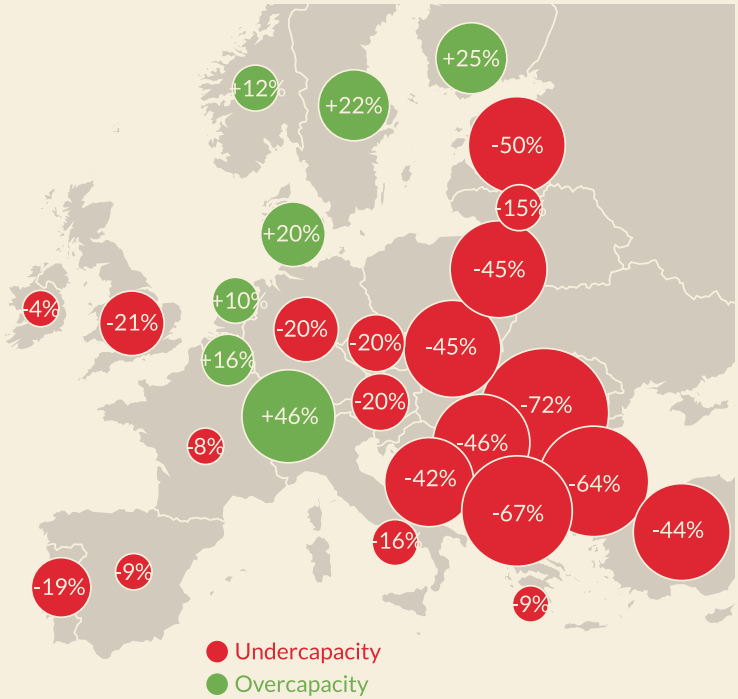
RADIOTHERAPY

MANY LUNG CANCER PATIENTS NEED RADIATION THERAPY BUT ACCESS TO MODERN RADIOTHERAPY EQUIPMENT DIFFERS AMONG COUNTRIES

Radiotherapy is an effective treatment to cure and prolong life, as well as to reduce symptoms and increase the quality of life of patients with advanced disease. But there are some disparities in the use of radiation therapy in Europe.[6] The QUARTS project, run by the European Society for Radiotherapy and Oncology (ESTRO), already showed in 2003 that the availability and need for radiotherapy services varies greatly from one European country to another.[7]

This fact was also remarked on by the European Network for Information on Cancer (EUNICE) project (2013), which analysed the radiotherapy centres in Europe to provide basic indicators for planning radiotherapy infrastructure and manpower at national and regional level.

Most European countries do not have the quantity or quality of radiotherapy facilities required to provide an adequate service to their populations, while some have more than enough



Slide from Tanja Cufer, presented at the session "Inequalities in access to treatments", ESMO Congress 2017. Data from Rosenblatt, E., et al., Lancet Oncol 2013.

> Despite the fact that thoracic surgery departments are present in many medical units all around the country [Romania], the radiation therapy facilities are under-represented and the access to this particular treatment modality is limited.
>
> **Mircea Dediu, Oncologist, Romania**

As the graphic shows, there is a significant disparity in the availability and organisation of radiotherapy services between countries. Some countries, such as the United Kingdom, Nordic countries and the Netherlands, have centralised service in a few cancer-care centres, providing all types of radiotherapy techniques, while in most of the European countries (28 out of 33 analysed) these facilities are fragmented, with many small centres with four or less machines.[8] In addition, and according to the EUNICE project, the quality and type of equipment differ between regions, and there is special need in Eastern and South-Eastern countries to expand and modernise their radiotherapy equipment.

WE ENCOURAGE MEDICAL PROFESSIONALS TO DESIGN A COMMON POLICY IN EUROPE TO GET ACCESS TO HIGH-QUALITY RADIOTHERAPY CENTRES ACROSS EUROPE AND PROVIDE THE BEST TECHNOLOGY AVAILABLE TO TREAT LUNG CANCER PATIENTS. A LACK OF RADIOTHERAPY SERVICES AND SHORTFALLS IN INFRASTRUCTURE AND HUMAN RESOURCES MUST BE FACED.

Disparities in access: Facing the problem

This report aims to raise awareness about disparities in order to implement solutions. We must reduce inequalities and get treatments available for patients and, as a first step, we all need to understand what are the main barriers to get faster access to treatment across Europe.

1. High costs of innovations

The cost of drugs with recent market approval is the first cause of inequity in regards to access to treatments.[9] The high cost of some of these treatments has produced differences in the ability of healthcare systems to reimburse all treatment options.[2] In addition, new treatments are often given alongside conventional treatment, increasing the overall cost of treating patients.[2] As new therapies are expected to become available in the future, combined treatments are likely to become the norm, thus increasing the costs and posing a major challenge for all health stakeholders.[2] In Europe alone, cancer is a major cause of morbidity and mortality.[10] In 2013, cancer represented 17% of the total burden of disease in Europe (as measured in disability adjusted life years [DALYs])[11].

Lung cancer has the highest overall economic cost of all cancer (15% of overall cancer costs) and it is the fourth of the highest health-care costs (8% of all cancer-related health-care costs). [36]

The financial impact of cancer is rising, with incidence projected to increase from 12.7 million (2008) to 21.4 million (2030).[12] However, we need to highlight that most of the economic burden of cancer is incurred in non-health-care areas (almost €43 billion in lost productivity attributable to early death) and only 27% of cancer-related health-care costs is attributable to drug expenditure. [36]

Sustainability of the European health systems is a major concern in this scenario. As representatives of lung cancer patients, we encourage regulatory bodies to guarantee patients drug accessibility and, at the same time, we are committed with national authorities to maintain the long-term financial sustainability of healthcare systems.

We want to ensure transparent and regulated drug pricing and reimbursement, as well as to improve transparency about the cost of research and the development of medicines. Some other proposals are to introduce flexible payment procedures (for instance, models of negotiated risk sharing or differential prices), set new approaches in pricing based on the assessment of added value and cost-effectiveness of drugs, and harmonize HTA approaches.

2. Differences in national economic strength

Economic strength and the human development index have been

found to contribute to access to treatments.[2] A 2016 report published by the Institute of Health Economics highlighted that variations between the national uptake of lung cancer treatments depend on a country's income-level, such as its GDP indicator.[2] The high cost of drugs approved in recent years has prominently affected countries with lower levels of economic development, particularly in Eastern Europe,[9] where there are more barriers to access to novel drugs.

Moreover, variation in implementation of national policies aiming at evidence-based as well as cost-effective care also results in differences among countries with a similar economic level.[2] Disparities in both financial resources and allocation of services, within and between countries, lead to 'patchy' coverage, and in turn disparities in survival rates within and between borders.

Oncology expenditure as a proportion of healthcare expenditure overall has remained stable at around 6%, despite the increasing number of people diagnosed. Portugal's level of investment has remained below average at 3.9%, along with a number of other countries.[13] This small proportion does not reflect the major and rising contribution of cancer to the total disease burden. This also means that tight budgets restrict the well-financed administration of drugs.

3. Regulatory barriers

Delays in patient access vary across Europe and often depend on the country and the setting where the drugs are used.[14] While the EU has adopted a common procedure for granting market authorisation to cancer medicines, which is obligatory for oncology drugs, pricing and reimbursement decisions reside with national governments/agencies. Despite an EU Directive on pricing and reimbursement that specifies a 180-day limit post company submission for price[15], compliance with this deadline is extremely variable.[2] Delays are shortening and have fallen in all countries (except Greece) from an average of 524 days in 2008 to 281 days in 2012. [37]

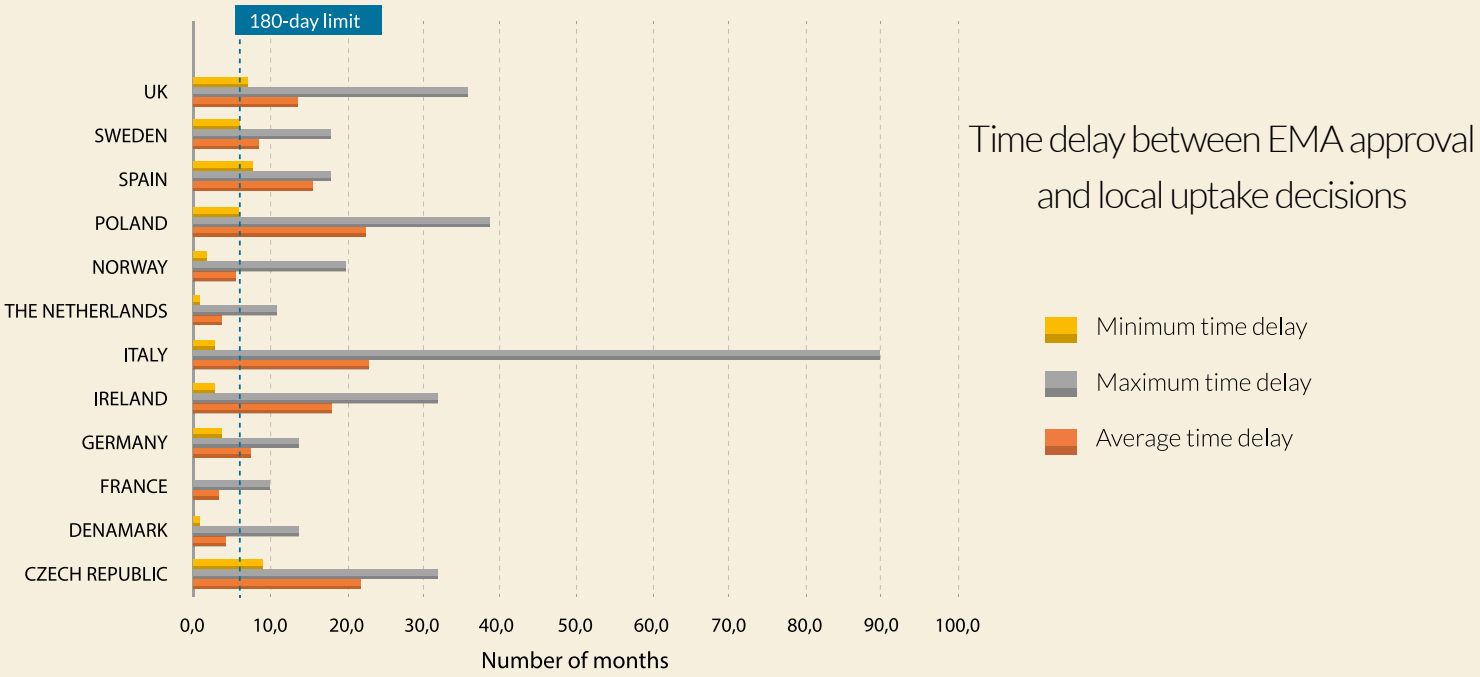
Beyond the EU framework, regulatory barriers such as different bureaucratic processes result in delays in patients having access to these medicines.[16] For example, regulatory delays in Turkey are attributed to lengthy Good Manufacturing Practice (GMP) approval.

There are significant time variations between countries' national decisions on lung cancer drug prices. The next graphic compares the time lag between EMA approval and local uptake decisions concerning the use of afatinib, necitumumab, ceritinib, erlotinib, gefitinib, nintedanib, nivolumab, osimertinib, pembrolizumab, ramucirumab and pemetrexed in [12] countries across Europe, showing significant differences.

Delays in ensuring patient availability following positive EMA approval were observed (e.g., delays were observed in the national approval of osimertinib in Italy and Poland). According to this data,

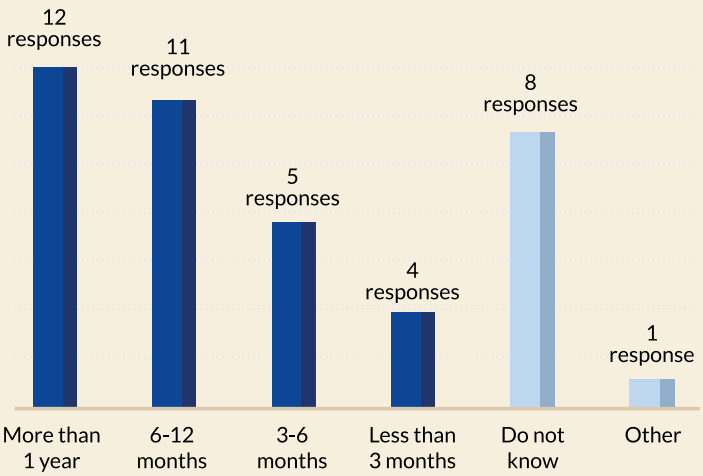
from the selected countries, only in Norway, The Netherlands, France and Denmark, the average time is under the 180-day limit set by the EU Directive.

The results of our research, completed by HCPs from 19 Organisation for Economic Co-operation and Development (OECD) countries, also evidence variations in the average time between new lung cancer drug approvals and reimbursement (see graphic on the next page). Variations in the average time vary from less than three months for Denmark, six to twelve months for Switzerland, Italy and France, to more than twelve months in Romania, the Netherlands and Spain. When asked to comment on how the availability of novel anti-cancer drugs has changed in their countries, compared to five years ago, respondents gave mixed answers, with more than 50% of responders reporting that it is easier nowadays, more than 25 % reporting no change and finally more than 20% assessing that the availability of novel anti-cancer drugs has actually decreased in their country in the past five



years. For instance, one pulmonologist from the Netherlands commented on the increased legislation and limited flexibilities of insurance and governmental organisations for personalised medicine as being the causes for stagnancy.

Average time between new drug registration/approval and endorsement/ reimbursement in the country



PRICING AND REIMBURSEMENT DECISIONS

The reasons why these delays happen across Europe are mainly pricing and reimbursement decisions, and disparities in delays happen because the ability and willingness to pay for medicines differ between member states.[2]

A study published by Europe Economics in 2013 assessed the impact of external reference pricing (ERP) on access of EU citizens to patented medicines and it found that the lack of coordination between member states on methodologies and criteria for taking decisions on pricing/reimbursement of medicinal products created incoherencies and delays in access to innovative medicines.[2] Additionally, the time that companies take to submit an application to national authorities, which 'starts the clock' of 180 days for national decisions on pricing and reimbursement,[17] may also delay the reimbursement process.

Theoretically, Germany and the UK have no reimbursement delays after EC approval; nevertheless, medicine uptake in the UK can vary dramatically because of the Health Technology Assessment (HTA) process. For example, first launched in late 2004, the reimbursement of Pemetrexed was significantly delayed (1-3 years) in the UK by the indications of Malignant Pleural Mesothelioma (MPM).

Other countries also have substantial delays on account of formal reimbursement procedures, including France, Belgium, and

Italy.[2] According to one of our respondents, following market authorisation of nintedanib in Ireland, the drug was reimbursed [27] months after approval, effectively leaving patients without access to an approved treatment option for more than two years.

With increasing costs of novel anti-cancer drugs, it is important to realise that not all improvements are equally important for all patients. Therefore, ESMO developed a tool, entitled MCBS (Magnitud of Clinical Benefit Scale) that might help patients and doctors when deciding about the value of novel therapy for each individual patient. In addition, MCBS also indicates which novel therapies passed a high threshold of clinical benefit set by MCBS and should be available to all patients without any major delay.[38]

–PRICING AND REIMBURSEMENT DECISIONS RESULT IN EUROPEAN PATIENTS HAVING ACCESS TO INNOVATIVE MEDICINES AT DIFFERENT TIMES–

Policies on inequalities in access to innovation

Access to innovative oncology medicines has been firmly on the top of the EU health policy agenda in the past ten years. Policymakers and civil society have been increasingly vocal on the need for transparency of cancer drugs prices as well as the need to ensure patient access to innovative medicine in constrained resource settings.

The ongoing issue of access to innovative oncology treatments, which had already been a priority for the Belgian presidency of the EU in 2010, gained further momentum in 2016, when the rotating Dutch presidency adopted the Council's conclusions on strengthening the balance in the pharmaceutical systems in the EU and its member states, asking the European Commission to undertake a critical review of the impact of current intellectual property (IP)-related incentives on biomedical innovation.

The European Parliament responded with the adoption of the European Parliament's own initiative report on EU options on access to medicines, which touches upon various dimensions of access to medicines, including research and development, intellectual property, pharmaceutical competition, pricing and transparency. In recognition of the urgency of the issue, the adoption of the report in the European Parliament Plenary of March 2017 saw a lively debate by MEPs on the measures needed at EU and national level for ensuring the availability and affordability of medicines, including lung cancer drugs

Policy in practice: CEE and Southern EU Countries joint procurement of medicines

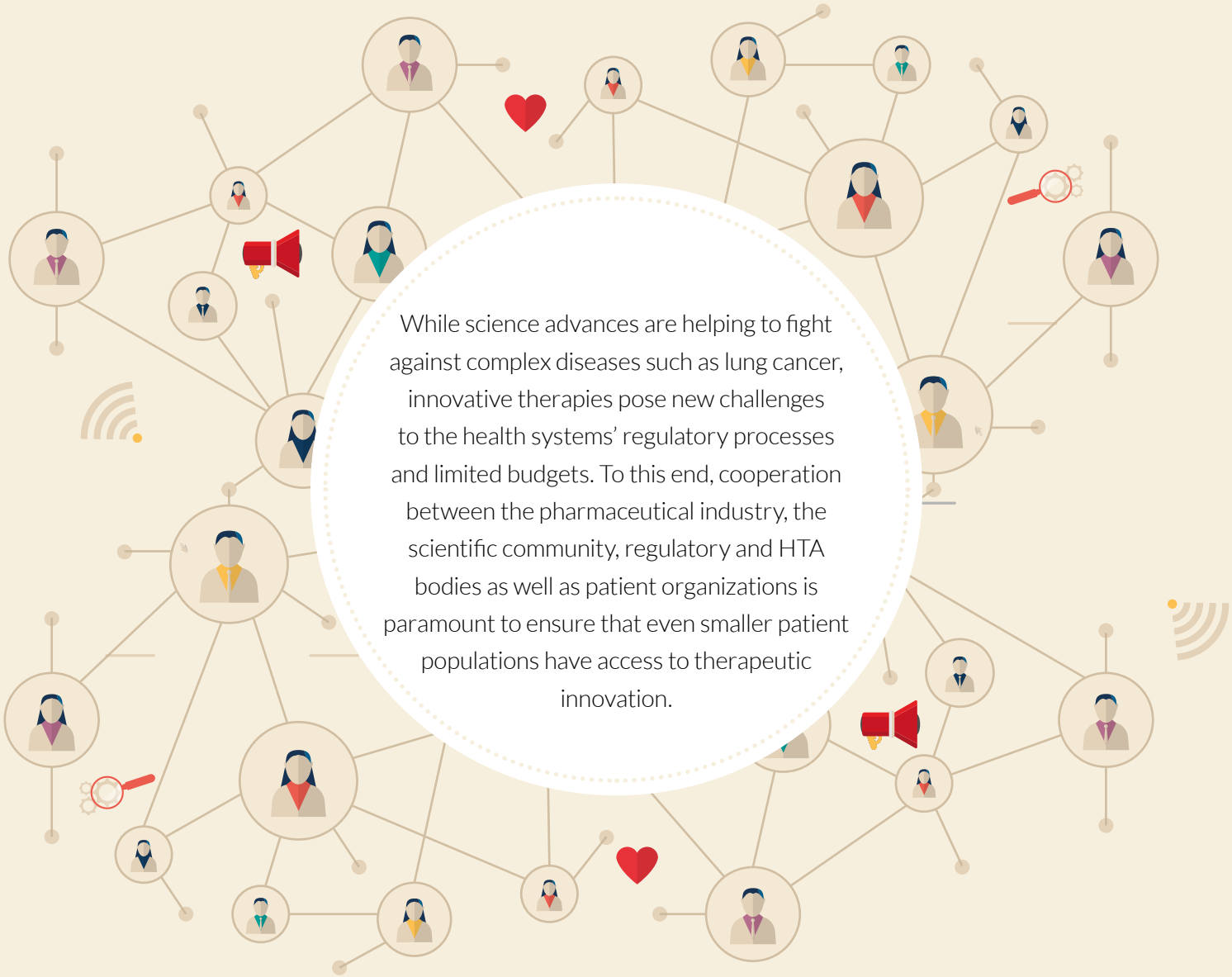
In a bid to achieve economies of scale, there is growing political will to launch joint negotiations for innovative medicines. A report published by the World Health Organization (WHO) Regional Office for Europe in 2016 [51] examined how access to medicines can be improved further by countries collaborating in the procurement of medicines.

The report highlights that joint purchasing partnerships can take place at different levels, varying with participating countries sharing information on prices, suppliers and Health Technology Assessment (HTA) methodologies. Countries across Europe have already joined efforts to form a number of these collaborative initiatives. Examples include:

- **BeNeLuxA:** A collaboration on the procurement of pharmaceuticals for rare diseases, involving Belgium, Luxembourg, and the Netherlands, started in 2015, with Austria joining in 2016.

- **Sofia Declaration:** Led by Bulgaria and signed by Croatia, Estonia, Hungary, Latvia, Macedonia, Romania, Serbia, Slovakia and Slovenia. It includes joint negotiation in purchasing and cross-border exchange of medicines in short supply.

- **Valletta Declaration:** Signed by the Health Ministers of Spain, Italy, Greece, Portugal, Cyprus, Malta, Romania and Ireland in May 2017. The Valletta Declaration launched a working group composed of the Ministers of Health of the aforementioned countries seeking agreement on joint procurement and calling for further price transparency to curb inequality in access across countries.



While science advances are helping to fight against complex diseases such as lung cancer, innovative therapies pose new challenges to the health systems' regulatory processes and limited budgets. To this end, cooperation between the pharmaceutical industry, the scientific community, regulatory and HTA bodies as well as patient organizations is paramount to ensure that even smaller patient populations have access to therapeutic innovation.

3. CARING FOR LUNG CANCER PATIENTS: HOW TO ENSURE AN INTEGRATED APPROACH

A lung cancer patient's journey is complex. It is not only about finding the appropriate treatment but also about getting the best care to address the different needs associated with the disease. No matter where they live, all patients need high-quality health assistance that may provide them care, support and information.

As countries attempt to improve the outcomes and cost-effectiveness of their health systems, it is necessary to consider what is meant by high quality treatment for lung cancer. Treatment must be of a high quality, safe and reach its purpose of simultaneously improving survival and the patients' quality of life. There is also a need to ensure the same high standard of care not only across, but also within countries.[17]

Once patients receive a correct diagnosis, they still have an extremely challenging disease journey ahead. No matter what stage of the cancer, receiving timely treatment to manage the side effects and symptoms is imperative. Patients usually require long-term treatment, hospital visits and stays, alongside attentive health personnel, to treat both their condition and the associated co-morbidities. Many patients leave the treatment pathway before receiving the help they need. Much of this is caused by gaps exist between primary and secondary care. Therefore, there is an important role for care coordinators to play in providing patients with support throughout the treatment journey.

Access to specialized centres, multi-disciplinary teams and palliative care become a priority when someone is diagnosed with lung cancer.

Specialised centre and multi-disciplinary teams

There is growing recognition of the need to streamline therapeutic pathways to improve the lung cancer patient's journey. Specific areas of focus should include: developing the information flow among primary, secondary and tertiary care; strengthening and consolidating multi-disciplinary approaches; improving pathway performance elements such as referral, waiting times and the length of in-patient treatment at each stage of care.

> *IT IS CRUCIAL TO FOSTER INTEGRATION BETWEEN SMALLER CANCER UNITS AND LARGER REFERENCE CENTRES, SO THAT PATIENTS WHO LIVE IN REMOTE AREAS HAVE THE SAME ACCESS TO SPECIALIST EXPERTISE AS PATIENTS IN LARGE URBAN AREAS*
>
> ***STEFANIA VALLONE, PRESIDENT OF LuCE***

Ensuring equal and faster access to lung cancer care (diagnosis and treatments) and the sustainability of health systems requires the development and accreditation of lung cancer specialised centres in Europe, allowing more patients to access specialised comprehensive care for lung cancer.[18] Furthermore, it is essential to make sure that these specialised centres have a high level of expertise and knowledge in order to offer specialised care centres.[19]

The Global Lung Cancer Coalition Patient charter calls for lung cancer patients to have the right to have access to optimal treatment, as suggested by a multi-disciplinary team of medical professionals that possess specialist knowledge about lung cancer.

Our survey among patient advocates shows that this multi-disciplinary approach is being taken up in several EU countries, but we highlight the status of lung cancer care in Romania, which is particularly critical. The lack of a multi-disciplinary approach in treating a patient with lung cancer, the lack of doctors and specialised nurses and the lack of patient information on their rights and options are among the main factors influencing patients' and carers' quality of life in a negative way in this country.

In lung cancer care, inequalities exist within European countries. For instance, this is the case in Italy, where disparities in standard of care, including the presence of specialised centres and multi-disciplinary teams, differs between southern and northern regions, impacting survival rates.[20]

LUNG CANCER IS A RAPIDLY PROGRESSING MALIGNANCY, WHICH PUTS FORTH A CHALLENGING NEED FOR AN EARLY DIAGNOSIS, WHILE THE DISEASE IS STILL IN THE CURATIVE STAGE.

TO TACKLE IT, A MUCH MORE HARMONIZED APPROACH IS REQUIRED, WITH COLLABORATION BETWEEN PRIMARY AND SECONDARY CARE SERVICES BEING THE ABSOLUTE KEY TO SUCCESS. IT IS ALSO VITAL TO ENSURE THAT CLINICIANS, CIVIL SOCIETY AND DECISION MAKERS MORE COMMONLY ENCOURAGE PATIENTS TO ACT EARLY ON – AT THE MOMENT WHEN SYMPTOMS APPEAR. AN EXAM MORE BEATS ONE FEWER!

TANJA CUFER, PROFESSOR OF ONCOLOGY (SLOVENIA)

WHY DO LUNG CANCER PATIENTS NEED MULTI-DISCIPLINARY TEAMS?

Lung cancer patients are at a high risk of co-morbidities, thus they need additional support, treatment and care. This is also needed to manage treatments in a way that optimises therapy and manages the side effects for each condition without compromising the treatment of another. A multi-disciplinary team is also needed to manage the overall impact on quality of life; for example, research has found that the presence of nurse coordinators improved the patient experience of the lung cancer treatment journey.

While multi-disciplinary teams (MDT) typically refer to medical staff, it is also important to consider the benefit of broader support networks, such as patient organisations. They can help the patient engage more effectively with their care team and provide psychosocial support to improve patients' and caregivers' quality of life. They can support a patient's journey and so help to avoid them dropping out of treatment.[2]

Multi-disciplinary team (MDT)

Thoracic surgeons + Medical oncologists + Radiologists + Pathologists + Nurses + Respirologists + Nutritionists + Psycho-oncologists + Palliative care specialists + Social workers

Palliative care

Palliative care is an important public health issue, largely neglected on the health policy agenda. However, it presents urgent public health challenges for healthcare stakeholders and patients.[21]

According to the WHO Regional Office for Europe, traditional palliative care has been centred on the needs of patients and their families at the end of life.[21] In lung cancer, palliative care is especially important, as around 80% of patients with lung cancer are at stage IIIB or IV of the disease when diagnosed, therefore excluding them from potentially curative treatments and surgery.[22]

The definition of palliative care differs across Europe. A survey conducted by the European Association for Palliative Care (EAPC) found some common structures, but also a wide variety in service development and care delivery, which is considered to be related to the different understanding of the underlying concept of palliative medicine.[23]

Access to palliative care varies across Europe, with the highest concentration of units being found in Ireland, Iceland and Belgium, followed by the UK, Sweden, Netherlands, Poland and Austria.[24] According to data on indicators for palliative care developed by EAPC, the availability of palliative care has improved in Eastern Europe over the last five years in countries such as the Republic of Moldova, Romania and Poland.[24]

> *80% OF THE TREATMENT RECEIVED BY A CANCER PATIENT IN POLAND IS PALLIATIVE CARE. IN LUNG CANCER, THIS NUMBER MIGHT BE EVEN HIGHER*
>
> ***EWELINA SZMYTKE, VICE-PRESIDENT OF LuCE***

Given the importance of palliative care, it will be of the utmost importance for national policymakers to invest in providing publicly funded palliative care services as a core part of healthcare services.[21]

LET´S CHAMPION A NEW DEFINITION OF PALLIATIVE CARE

The perception of palliative care among patients with advanced cancer and their caregivers affects early access to services.[25] Although a number of studies have shown that early involvement of specialised palliative care services for patients with advanced cancer improves quality of life, leads to higher satisfaction with care and provides psychological support, referrals to palliative care are typically made late in the disease's course.[25] Negative perceptions and attitudes towards palliative care are often cited by healthcare professionals (HCPs) as a reason for late referrals to palliative care.[25]

Another study assessing the perception of palliative care found that it is associated with the last weeks of life.[26] Other findings of the study found that although some patients, families and friends referred to the control of symptoms and quality of life, it is usually in the context of end-of-life care.[26]

As lung cancer is usually diagnosed late, most of the patients are treated with palliative drugs. They cause the tumour shrinking. Sometimes it may lead to a complete cure, but usually it's a treatment aimed at prolonging the life in best possible quality of life.

Therefore, all stakeholders, including patient groups and HCPs, should work together to fight the misconception that narrows down palliative care to 'end-of-life care' and champion a broader definition of palliative care that accompanies the patient throughout their therapeutic pathway. Most lung cancer patients are treated with palliative drugs, aiming to prolonging their lives with the best quality of life possible. There are common misunderstandings regarding palliative care, as it is generally associated with treatment at the end of life. However palliative care is a multi-disiciplinary approach aimed to improve the quality of life and reduce symptoms. Therefore it is important to raise awareness about the proper definition of palliative care.

Palliative care also includes the end of life care and there is a need to take into consideration assisted living and the right to die at home. In countries such as the Netherlands, the government has specified that the provision of end-of-life care should be part of the professional skills of all physicians, including general practitioners (GPs), to ensure that the best care is given to patients who are staying at home.[26]

4. LUNG CANCER POLICIES

NATIONAL LUNG CANCER PLANS: PROMOTING PUBLIC HEALTH PROGRAMMES

A National Cancer Plan is a public health programme designed to reduce the number of cancer cases and deaths and improve the quality of life of cancer patients, through the systematic and equitable implementation of evidence-based strategies for: prevention, early detection, diagnosis, treatment, rehabilitation, palliation and research to search for innovative solutions and evaluate outcomes (European Partnership for Action Against Cancer)

In 2008, the EU Council Conclusion on reducing the burden of cancer[27] called upon each member State to develop and implement comprehensive cancer strategies or plans. One year later, the European Commission launched the European Partnership for Action Against Cancer (EPAAC) to support this decision.

The EPAAC drew on the expertise of academics, health professionals and non-governmental organisations (NGOs), as well as the WHO and OECD, to support EU countries in developing national cancer control plans (NCCPs).* The EPAAC database provides an overview of those national cancer plans in place in Europe.**

An analysis of the EPAAC database reveals that the level of detail on lung cancer in national cancer plans varies significantly from one country to another. Only eight NCCPs have specific provisions on lung cancer.

* The initiative, completed in 2014, was followed by another EU-funded consortium: CanCon, which is currently working on dissemination of the European Guide on Quality Improvement in Comprehensive Cancer Control https://cancercontrol.eu/archived/

** Own research added to the European Partnership for Action against Cancer database information

Some countries, like Slovenia and Austria, set specific objectives to fight lung cancer. In Austria, such objectives are mostly related to prevention, which includes environmental prevention, tobacco control and exposure to carcinogens.[28] Slovenia has set specific targets in relation to the improvement of health systems services and infrastructures, e.g., the creation of diagnostic centres for lung cancer and the establishment of standard endoscopic procedures for the treatment of patients with suspected lung cancer.[29] Most national plans with specific provisions on lung cancer mention smoking cessation and prevention as the main preventive measure and target of their lung cancer policies.

However these measures are not accessible and not always effective. In Poland, for example, there are not enough support services for smokers who want to quit. And there are some regulations that limit the use of these resources – for example, if a smoker once, he/she will not be able to use it again if this attempt to quit smoking has not been successful the first time.

PREVENTION: FIRST STEP IN TACKLING THE INCREASING BURDEN OF LUNG CANCER

Significant lung cancer incidence is attributable to smoking, underlining the importance of investing in anti-smoking and smoking cessation campaigns.[2]

Looking at smoking cessation policies to date, there is evidence that smoking bans have been highly impactful interventions. While it may take 20–30 years to have the complete picture, the evidence from smoke-free countries is encouraging: indoor air quality improved dramatically after smoking bans came into effect, with an 83% and 86% reduction in the concentrations of particulate matter in Irish and Scottish bars, respectively. Better air quality has led to a significant drop in heart attacks: 11% fewer in Ireland and Italy, a 17% drop in Scotland, and even greater reductions in some US jurisdictions.[30]

–SMOKE-FREE POLICIES REDUCE TOBACCO CONSUMPTION AND ENCOURAGE SMOKERS TO QUIT–

Numerous studies have also shown significant improvement in the respiratory health of workers in the hospitality sector as a result of smoke-free laws.[30] There are also reports that smoke-free policies have reduced tobacco consumption and encouraged smokers to quit.[30]

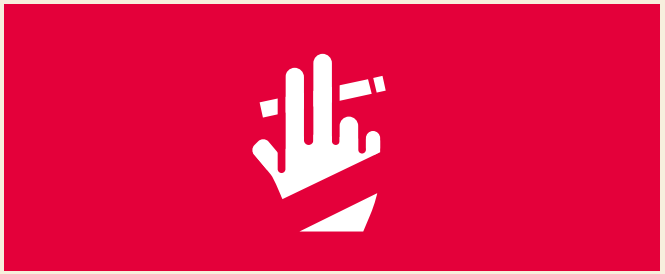
Oncologists and public health professionals suggest that both educational and smoking cessation programmes should address the change in the smoking population, for instance, by targeting teenagers and young women.

Lung cancer prevention plans must consider and avoid stigma around lung cancer, largely based upon its association with smoking and thus with being a self-inflicted disease. This can cause barriers to individuals acknowledging their symptoms, and families providing the necessary support to ensure patients continue their treatment pathway. The stigma associated with lung cancer can also be found in non-smokers. Research confirmed that among lung cancer patients who have never smoked, the majority are women, yet they face the same stigma. [31-32] This research also suggested that patients can experience a sense of guilt induced by the economic burden and impact on their quality of life and the work of their families and carers.[31-32]

SWITZERLAND

Policy in practice — the Swiss Tobacco Prevention Fund

- The Tobacco Prevention Fund has the overall objective to reduce tobacco consumption in Switzerland and to ensure sustainable tobacco prevention. It includes different prevention measures that help to curb tobacco consumption.



- The Tobacco Prevention Fund is financed through a levy on every cigarette package. Every year, 13.5 million Swiss francs are available for tobacco prevention, of which 20-30% is used for physical activity projects. Around 22% of the fund is used to promote smoking cessation and 25% is used for public awareness. The remaining money is used for the prevention of smoking, protection from passive smoking, the interconnection of the organisations and for support of research. An external evaluation has showed that the fund is well organised and complements the national tobacco strategy.

According to the WHO, primary prevention policies should also encompass the elimination, or reduction of, exposure to recognised risk factors in susceptible populations.[33] For example, control measures to reduce air pollution from traffic, decrease exposure to diesel exhaust gases, and ban the use of asbestos may contribute to the prevention of lung cancer. To this end, the WHO calls upon policymakers to establish links between public health programmes for the prevention and control of cancer, and programmes and plans of action in the areas of occupational health, environmental health, chemical safety and food safety.[33]

OCCUPATIONAL HEALTH AND LUNG CANCER

What is the issue?	The total burden of lung cancer cases attributable to work-related exposure to respiratory carcinogens in Europe has been estimated to be 32,400 cases per year. Despite such high estimates, very few lung cancers of occupational origin are reported. There are several reasons for such under-reporting: occupational lung cancer almost always occurs among (former) smokers; the clinical presentation of occupational lung cancer is generally similar to that of non-occupational lung cancer; therapeutic options do not differ between occupational and non-occupational lung cancer.
What is being done?	The European Lung Foundation and the European Respiratory Society (ERS) are working together with the help of other lung cancer patient representatives to provide information on symptoms, the latest available treatments and research to people who are worried about the impact of their workplace on their lung health. The aim is to help workers exposed to dangerous substances recognise the symptoms of lung diseases, including lung cancer, and seek help as early as possible.
What should be done?	The notion of occupationally induced lung cancer is important in terms of prevention, and European efforts to detect and reduce occupational carcinogenic exposures must continue.

RESEARCH AND NETWORK: COMMITMENT TO SCIENCE

EU-funded research in the field of lung cancer focuses mainly on supporting studies on the use of biomarkers for earlier diagnosis. In 2011, the EU fund for innovation, Horizon 2020, allowed the launch of the project CURELUNG, completed in 2013. Bringing together European specialists in genetics, epigenetics, pathology and oncology, the initiative identified several epigenetic lung cancer biomarkers that could be useful to target new therapies and early diagnosis.

–PROJECT "CURELUNG" HAS CONTRIBUTED TO THE WORLD´S LARGEST MOLECULAR SCREENING NETWORK FOR LUNG CANCER–

The project has also contributed to the world's largest molecular screening network for lung cancer, the Network Genomic Medicine. Such initiatives show the huge potential of cross-border collaboration in oncology research and impact on the life of people living with cancer. To this end, it is essential that new EU funding mechanisms for innovation, such as the upcoming FP9, will give researchers the possibility to continue co-operation in the area of lung cancer, with specific calls for lung cancer research and innovation.

European-level health professional groups, such as the European Respiratory Society (ERS), have been active in connecting researchers and helping bring stakeholders together to assess the status and quality of care in lung cancer. The ERS Task Force report, published in 2014, outlined the first phase of an initiative aimed to improve the quality of care for people with lung cancer across Europe. Members of the Task Force have, therefore, proposed further research and development of a project whereby the ERS, in collaboration with other professional bodies, have begun developing a network for European lung cancer centres, steered by a committee composed of members of the ERS Thoracic Oncology Assembly. The work of members includes epidemiology and prevention, biology and pathology, diagnosis and staging, multi-disciplinary approaches in therapy, systemic treatment with chemotherapy and targeted agents, and follow-up and supportive care.

PROFESSIONAL LUNG CANCER GUIDELINES: LOOKING FOR COMMON STANDARDS OF CARE

One of the key areas likely to influence the quality of lung cancer care is the use of guidelines to set standards of care. Quality might be influenced by the availability of a guideline, its content, and whether a guideline, where available, is implemented or not. In turn, the latter may be influenced by the willingness to implement the guideline and by organisational, political and socioeconomic factors.[34]

Most countries refer to international guidelines for lung cancer treatment. The European Society for Medical Oncology (ESMO), the American Society of Clinical Oncology (ASCO), the International Association for the Study of Lung Cancer (ISLAC), the European Lung Cancer Working Party (ELCWP), the European Organisation for Research and Treatment of Cancer (EORTC) and the ERS/European Society of Thoracic Surgeons (ESTS) are the main points of reference for international guidelines, with ESMO having updated their guidelines in June 2017.

ESMO guidelines focus on diagnosis and personalised medicine, staging and risk assessment and management of advanced/ metastatic NSCLC, including follow-up.[35]

–NOT ALL COUNTRIES HAVE LUNG CANCER GUIDELINES–

PATIENT ENGAGEMENT AND INVOLVEMENT IN POLICY AND ADVOCACY

While multi-stakeholder efforts to date provide the building blocks to create patient-centric policies, there is still a long way to go to ensure actual patient inclusion in policy design, as well as in pricing and reimbursement policies. Our survey of lung cancer groups and HCPs across Europe reveals that patient groups have little or no involvement in national decisions on novel anticancer drugs reimbursement and uptake, and even less on HTA assessments.

–PATIENT GROUPS HAVE LITTLE INVOLVEMENT IN HTA APPRAISALS–

The reasons are linked to the lack of a formal mechanism for their involvement on a national level and a lack of necessary expertise to participate in the HTA process. These findings suggest that we need to continue upscaling our skills to truly have the capacity to influence policymaking.

Some EU-wide initiatives have sought to address this problem over the last few years. An example is represented by the patient training initiatives on patient involvement in HTA offered by the European Patient Academy (EUPATI). These initiatives need to be complemented by policymakers' commitment to create formal processes for patient engagement in pricing and reimbursement, better information on engagement opportunities, and continued patient group efforts to consistently collaborate with governments.

Along with the effort of policymakers, stakeholder partnerships comprising industry, patient groups and medical societies are working on providing evidence-based policy solutions on how to strengthen healthcare systems and ensure access to innovation. Noticeable examples are the European Cancer Patient Coalition White Paper on the Value of Innovation in Oncology, launched at the European Cancer Congress 2017 in Amsterdam. The report makes recommendations to EU and national policymakers for sustainable and equitable access to innovative cancer treatments and care pathways.

Another example is the report of the All.Can* initiative towards sustainable cancer care: reducing inefficiencies and improving outcomes, launched in January 2017. The report looks at improving efficiency in cancer care as a means of securing better health outcomes for patients and making better use of available resources as a result. It examines where system inefficiencies exist, collects examples of good practice, including on lung cancer, and derives lessons from them to help trigger policy action.

LuCE is the voice of lung cancer across Europe, so we are committed to working with the European institutions, national governments, economists, regulators, the pharmaceutical industry, healthcare organisations, the media and society, to ensure that lung cancer is being prioritised in legislation and regulations.

THE ROLE OF HTA IN PATIENT ACCESS TO HEALTH TECHNOLOGIES HAS INCREASED. PATIENTS AND THEIR ASSOCIATIONS SHOULD BE INVOLVED IN THE HTA PROCESS FOR AT LEAST TWO REASONS. HTA ADOPTS A MULTI-CRITERIA APPROACH, INCLUDING BENEFITS BEYOND CLINICAL VALUE, I.E., PATIENTS' REPORTED OUTCOMES, ACCEPTABILITY TO PATIENTS AND PATIENTS' PREFERENCES: PATIENTS MAY PROVIDE AND DISCUSS EVIDENCE ON THESE BENEFITS.

HTA IS A MULTI-STAKEHOLDER PROCESS TOO: PATIENTS ARE THE MOST IMPORTANT STAKEHOLDERS SINCE THEY ARE THE ULTIMATE BENEFICIARY OF HEALTH TECHNOLOGIES. THEIR ROLE GOES BEYOND ASSESSMENT: THEY SHOULD ALSO BE ENGAGED IN THE APPRAISAL PROCESS — REIMBURSEMENT/ RECOMMENDATION OF HEALTH TECHNOLOGIES. PAYERS MAY BENEFIT FROM THIS, SINCE THEY WOULD HAVE PATIENTS (AND THE OTHER RELEVANT STAKEHOLDERS) ALIGNED WITH DECISIONS TAKEN.

CLAUDIO JOMMI, HEALTH ECONOMIST

* All.Can is a multi-stakeholder platform established to create political and public engagement on the need to improve efficiency in cancer care. Participants include patient and professional groups and the pharmaceutical industry. A full list of members is at: http://www.all-can.org/members/

5. CALL TO ACTION

LET´S REDUCE DISPARITIES: WHAT MUST WE DO?

Close the current gaps in access

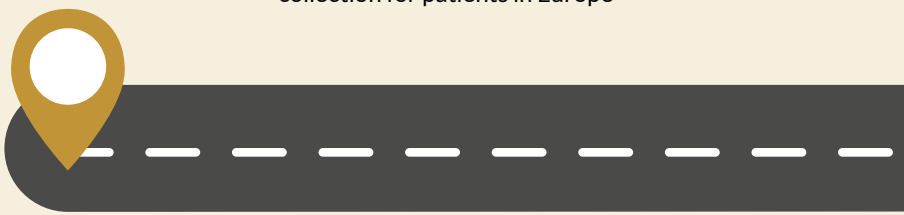
Shorten the time for new drugs to be introduced in member States + Ensure the access of patients to clinical research across borders + Harmonize HTA approaches

Collection of systematic data

Collect patient data to identify unmet needs + Monitor the correct implementation of the EU Cross-Border Health Directive to ensure access to treatments + Improve and harmonize data collection for patients in Europe

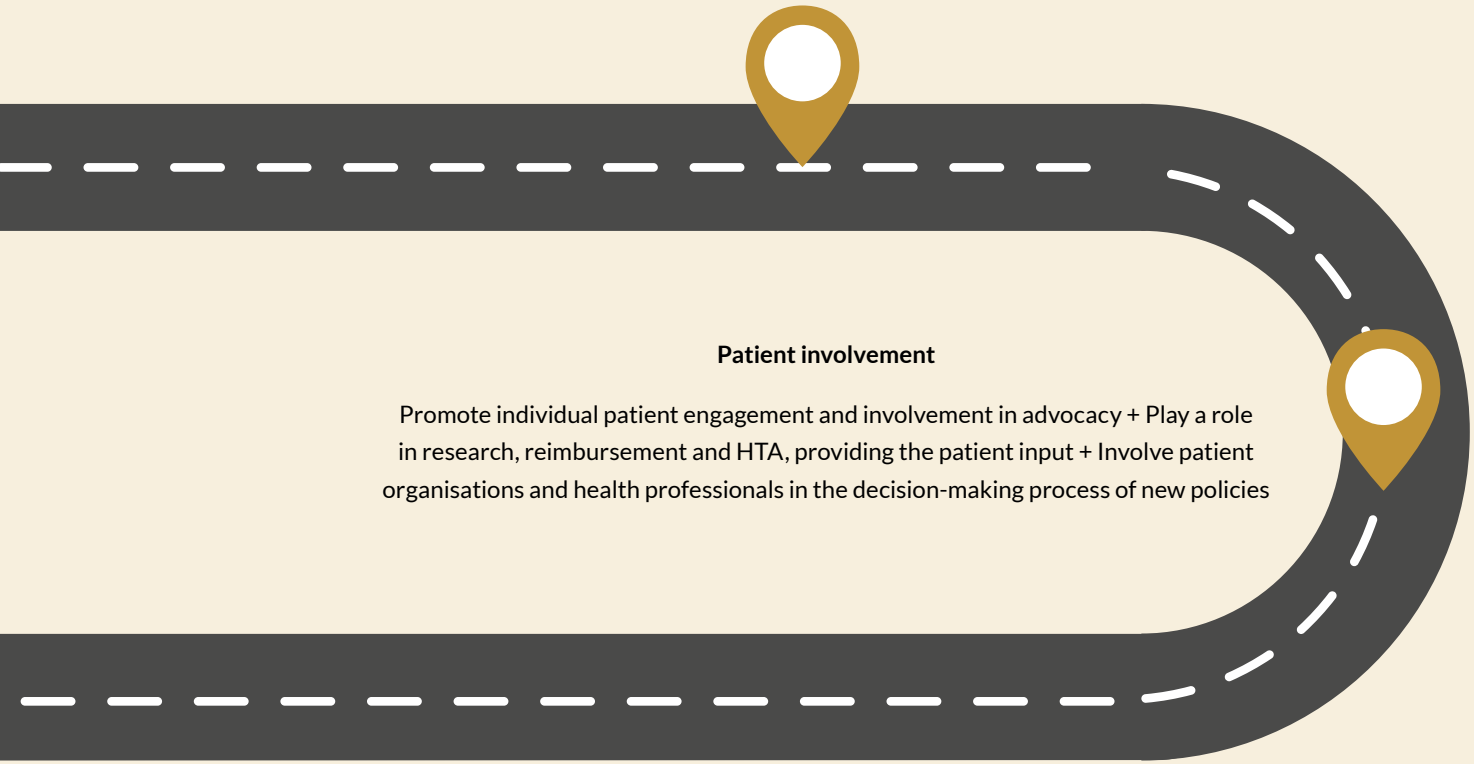
Common guidelines to set standards of care

Develop and harmonize guidelines on lung cancer across Europe + Ensure implementation of guidelines for lung cancer diagnosis and treatment + Develop uniform national lung cancer plans + Stimulate the development and accreditation of centres specializing in lung cancer across Europe, to create reference networks



Financial sustainability of healthcare systems

Improve transparency about costs of research and development of new drugs + Introduce new flexible payment procedures in pricing/reimbursement negotiations + Set a new approach in pricing based on the assessment of added value and cost-effectiveness of drugs for patients + Follow ESMO Score of Clinical Benefit when deciding on reimbursement policies + Ensure transparent and regulated drug pricing and reimbursement, and get more collaboration among nation states on price negotiations



Patient involvement

Promote individual patient engagement and involvement in advocacy + Play a role in research, reimbursement and HTA, providing the patient input + Involve patient organisations and health professionals in the decision-making process of new policies

DIFFICULT ROADS OFTEN LEAD TO BEAUTIFUL DESTINATIONS

LET´S DO THE WALK TOGETHER!

SUPPORT OUR CALLS TO ACTION

On 16th November 2016, we held an event at the European Parliament (Brussels) to raise awareness among different stakeholders and engage them on the importance of addressing the challenges in lung cancer.

This meeting was held jointly with the Association of European Cancer League (ECL) and hosted by MEP Alojz Peterle, President of MEPs Against Cancer (MAC). Patient activists, politicians, physicians, patient advocates, journalists, pharmaceutical companies and other stakeholders participated. Different perspectives on the challenge of lung cancer in Europe were presented. This was a rare opportunity to involve many stakeholders and launch a call for action, encouraging the attendees to work together to foster improvements in early detection, accurate diagnosis, more effective and safe treatments, as well as faster access to innovative therapies, ensuring the sustainability of European health systems.

Further to the event, our calls to action were published on Euractiv with the support of 16 key European policymakers and patient advocates. This was just the beginning of our journey to support the 312,000 Europeans diagnosed with lung cancer each year.

To date, we are working with European institutions, national governments, economists, regulators, the pharmaceutical industry, healthcare organisations, the media and society, to ensure that lung cancer is being prioritised in legislation and regulations. As such, we need the support of all relevant stakeholders to continue delivering upon our commitment and gather support for our calls to action. Access to our website and support our call to action:

www.lungcancereurope.eu

Lung Cancer Europe

ABOUT LuCE

Lung Cancer Europe is the voice of lung cancer patients, their families and survivors at a European level. LuCE provides a European platform for already existing lung cancer patient advocacy groups and supports the establishment of national lung cancer patient groups in different European countries where such groups do not yet exist.

LuCE aims to raise awareness about inequities regarding the access to lung cancer treatment and care in Europe. Moreover, LuCE lobbys upon European policies aiming at improvements in lung cancer prevention, early detection, treatment and care. LuCE also supports national lung cancer patient groups in helping raise awareness for lung cancer among the European public.

OUR OBJECTIVES

- Reduce the mortality of lung cancer.
- Promote the best possible treatment of the different types of lung cancer.
- Equal access to lung cancer care throughout Europe.
- Raise public awareness for lung cancer about symptoms, early detection and treatment.
- Reduce the stigma associated with lung cancer and more compassion for lung cancer patients and their loved ones.
- Increase European funding allocated to lung cancer research.

ABOUT OUR MEMBERS

LuCE gathers its strength from the combined action of different national patient organizations across Europe. These organizations give support to lung cancer patients, defend their rights and represent their interests on an everyday basis. They are the voice of the patients in national and international forums, and their work benefits society as a whole. We are stronger together, thus we thank each and every one of the members of LuCE for their generous contribution.

We encourage readers to learn more about these organisations and support them.

Asociación Española de Afectados de Cáncer de Pulmón
www.afectadoscancerdepulmon.com

Bundesverband Selbsthilfe Lungenkrebs e.V.
www.bundesverband-selbsthilfe-lungenkrebs.de

Israel Lung Cancer Foundation
www.ilcf.org.il

Landesverband Baden- Württemberg für Lungenkrebskranke und deren Angehörige e.V

www.lungenkrebs-bw.de

Lungekreftforeningen

www.lungekreftforeningen.no

Pulmonale

www.pulmonale.pt

Longkanker Nederland

www.longkankernederland.nl

National Lung Cancer Forum for Nurses (NLCFN)

www.nlcfn.org.uk

Stowarzyszenie Walki z Rakiem Pluca

www.rakpluca.org.pl
www.rakpluca.szczecin.pl

Lungencancerförbundest Stödet

www.lungcancerforeningen.se

Patientforeningen Lungekræft

www.lungekraeft.com

Women Against Lung Cancer in Europe

www.womenagainstlungcancer.eu

ASSOCIATE MEMBERS

LuCE associate members are organisations committed to improve the lives of lung cancer patients. LuCE wishes to thank these organizations for their continuous support.

Društvo onkoloških bolnikov Slovenije

www.onkologija.org

European Thoracic Oncology Platform (ETOP)

www.etop-eu.org

European School of Oncology (ESO)

www.eso.net

Fundación MÁS QUE IDEAS

www.fundacionmasqueideas.org

Suomen Syöpäpotilaat - Cancerpatienterna i Finland ry

www.syopapotilaat.fi

Pembe Hanim Turkey

http://www.pembehanim.com.tr/

If you are interested in joining LuCE, please contact us.

We will be pleased to meet you!

luce@etop-eu.org

ABBREVIATIONS

ASCO	American Society of Clinical Oncology
EAPC	European Association for Palliative Care
ECL	European Cancer League
EGFR	Epidermal growth factor
EORTC	European Organization for Research and Treatment of Cancer
ELCWP	European Lung Cancer Working Party
EPPAC	European Commission launched the European Partnership for Action Against Cancer
ESMO	European Society for Medical Oncology
ERP	External reference pricing
ERS	European Respiratory Society
ESTS	European Society of Thoracic Surgeon
EU	European Union

EUPATI	European Patients Academy on Therapeutic Innovation
GMP	Good Manufacturing Practice
GP	General practitioner
HCP	Health care professional
HTA	Health Technology Appraisal
ICPIs	Immune checkpoint inhibitors
ISLAC	International Association for the Study of Lung Cancer
MAC	MEPs Against Cancer
MPM	Malignant Pleural Mesothelioma
NCCP	National cancer control plans (NCCPs
NGO	Non-governmental organisations
NSCLC	Non-small cell lung cancer
OECD	Organisation for Economic Co-operation and Development
TKI	Tyrosine kinase inhibitors
WHO	World Health Organisation

REFERENCES

1. PhRMA. A decade of innovation in cancer, 2006-2016. Available from: http://phrma-docs.phrma.org/sites/default/files/pdf/decade-of-innovation-cancer.pdf [Accessed October 2017].
2. LuCE. Challenges in lung Cancer Europe report. 2016. Available from: http://www.lungcancereurope.eu/wp-content/uploads/2016/11/LuCE-Report-final.pdf [Assessed October 2017].
3. Plun-Favreau J, Immonen-Charalambous K, Steuten L, et al. Enabling equal access to molecular diagnostics: what are the implications for policy and health technology assessment? Public Health Genomics. 2016;19:144-52. doi: 10.1159/000446532.
4. McKendrick J. Impact of licensing and reimbursement discrepancies on patient access to cancer treatments across Europe and Canada. Annals of Oncology (2017) 28 (suppl_5)
5. ESMO European Consortium Study on the availability, out-of-pocket costs and accessibility of antineoplastic medicines in Europe. Ann Oncol. 2016;27(8):1423-1443.
6. European Cancer Patient Coalition. Challenging the Europe of Disparities in Cancer. Available at: http://www.ecpc.org/Documents/Policy&Advocacy/Europe%20of%20Disparities/Europe%20of%20Disparities%2027th%20Sept%202015.pdf [Accessed September 2017]
7. Bentzen SM, Heeren G, Cottier B, et al. Towards evidence-based guidelines for radiotherapy infrastructure and staffing needs in Europe: the ESTRO QUARTS project.Radiother Oncol. 2005 Jun;75(3):355-65.
8. Rosenblatt E, Izewska J, Anacak Y, et al. Radiotherapy capacity in European countries: an analysis of the Directory of Radiotherapy Centres (DIRAC) database. Lancet Oncol. 2013 Feb;14(2):e79-86
9. Cherny N, Sullivan R, Torode J, et al (2016). ESMO European Consortium Study on the availability, out-of-pocket costs and accessibility of antineoplastic medicines in Europe. Annals of Oncology; 27 (8): 1423–1443
10. Jonsson B, Hofmarcher T, Lindgren P, Wilking N, Comparator report on patient access to cancer medicines in Europe revisited (2016). Available at: www.ihe.se/en/publicering/ cancer-medicines-in-europe-2 [Accessed August 2017]
11. Cole, A., Garrison, L., Mestre-Ferrandiz, J., & Towse, A. (2015). Data Governance Arrangements for Real-World Evidence. OHE Consulting Report, London: Office of Health Economics. Available at: www.ohe.org/publications/improving-efficiency-and-resourceallocation-future-cancer-care [Accessed August 2017]
12. Lawler M, et al (2014). A Catalyst for Change: The European Cancer Patient's Bill of Rights. The Oncologist 2014;19(3):217-24.
13. Jönsson B, Hofmarcher T, Lindgren P, Wilking N. Comparator report on patient access to cancer medicines in Europe revisited. IHE report 2016:4. Lund: Institute of Health Economics.

2015. Available at: http://lup.lub.lu.se/search/ws/files/11713673/IHE_Report_2016_4_.pdf [Accessed October 2017]

14. Ades F, Zardavas D, Senterre C, et al. Hurdles and delays in access to anti-cancer drugs in Europe. Ecancermedicalscience. 2014;8:482.

15. European Commission. Faster access of patients to new medicines — revised transparency directive. MEMO 12/148, 1 March 2012. Available at: http://europa.eu/rapid/press-release_MEMO-12-148_en.htm?locale=en [Accessed October 2017].

16. Nguyen TA, Knight R, Roughead EE, Brooks G, Mant A. Policy options for pharmaceutical pricing and purchasing: issues for low- and middle-income countries. Health Policy Plan. 2015;30:267-80.

17. Council of the European Communities. Council Directive of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems (89/105/EEC). Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31989L0105 [Accessed October 2017].

18. Lung Cancer Europe (LuCE). Position paper. 2015. Available at: http://www.lungcancereurope.eu/wp-content/uploads/2015/11/LuCE-EU-Policy-Position-Paper-2015-IMPAGINATO.pdf [Accessed October 2017].

19. Cancer Research UK. Lung cancer: symptoms. Available at: http://about-cancer.cancerresearchuk.org/about-cancer/lung-cancer/symptoms [Accessed October 2017].

20. Sant M, Minicozzi P, Allemani C, et al. Regional inequalities in cancer care persist in Italy and can influence survival. Cancer Epidemiol. 2012;36:541-7.

21. World Health Organization Regional Office for Europe. Palliative care: the solid facts. 2004. Available at: http://www.euro.who.int/__data/assets/pdf_file/0003/98418/E82931.pdf [Accessed October 2017].

22. Birring SS, Peake MD. Symptoms and the early diagnosis of lung cancer. Thorax. 2005;60:268-9.

23. Radbruch L, Payne S. European Association for Palliative Care. White Paper on standards and norms for hospice and palliative care in Europe: part 1. Recommendations from the European Association for Palliative Care. European Journal of Palliative Care. 2009; 16:278-89.

24. European Association for Palliative Care. New indicators demonstrate the increasing interest in palliative care throughout Europe. Press release 29 May 2013. Available at: http://www.eapcnet.eu/Themes/Organisation/DevelopmentinEurope/EAPCAtlas2013.aspx [Accessed October 2017].

25. Zimmermann C, Swami N, Krzyzanowska M, et al. Perceptions of palliative care among patients with advanced cancer and their caregivers. CMAJ. 2016;188:E217-27.

26. Van der Heide A, de Vogel-Voogt E, Visser AP, van der Rijt CC, van der Maas PJ. Dying at home or in an institution: perspectives of Dutch physicians and bereaved relatives. Support Care Cancer. 2007;15:1413-21.

27. Council of the European Union. Council conclusions on reducing the burden of cancer. Available at: http://www.eu2008.si/en/News_and_Documents/Council_Conclusions/June/0609_EPSCO-cancer.pdf [Accessed October 2017].

28. Bundesministerium für Gesundheit. Krebsrahmenprogramm Österreich 2014. Available at: https://www.bmgf.gv.at/cms/home/attachments/2/7/0/CH1480/CMS1412233312313/krebsrahmenprogramm.pdf.[Assessed October 20017].

29. Republika Slovenia Ministrtvo Za Zdravje. The National Cancer Control Program. Available at: http://www.mz.gov.si/fileadmin/mz.gov.si/pageuploads/zakonodaja/01122016_Osnutek_dokumenta_DPOR_2017-2021_FIN.pdf. [Accessed October 2017].

30. European Commission. Q&A: The Fight Against Tobacco in the EU. 2011. Available at http://europa.eu/rapid/press-release_MEMO-11-349_en.htm [Accessed October 2017].

31. NBC News. Lung cancer for nonsmokers still stained by stigma. Available at: http://www.nbcnews.com/health/cancer/lung-cancer-nonsmokers-still-stained-stigma-n246441 [Accessed October 2017].

32. Cataldo JK, Jahan TM, Pongquan VL. Lung cancer stigma, depression, and quality of life among ever and never smokers. Eur J Oncol Nurs. 2012;16:264-9.

33. World Health Organization (WHO). Primary prevention of cancer through mitigation of environmental and occupational determinants. Available at: http://www.who.int/phe/news/events/international_conference/Background_interventions.pdf [Accessed October 2017].

34. Blum TG, Rich A, Baldwin D, et al. The European initiative for quality management in lung cancer care. Eur Respir J. 2014;43:1254-77.

35. Blum TG, Rich A, Baldwin D, et al. The European initiative for quality management in lung cancer care: appendices. Available at: http://erj.ersjournals.com/content/erj/suppl/2014/04/17/09031936.00106913.DC1/ERS_TF_EIQMLCC_Appendices.pdf [Accessed October 2017].

36. Luengo-Fernández R, Leal J, Gray A, et al. Economic burden of cancer across the European Union: a population-based cost analysis. The Lancet Oncology 2013;14 (12): 1165-1174.

37. Flostrand SJ, Lor S, Anon Y. Trends in time to market access in Europe. Is it getting better. Value Health 2014; 17 (7).

38. Cherny N, Sullivan R, Dafni U, et al. A standardised, generic, validated approach to stratify the magnitude of clinical benefit that can be anticipated from anti-cancer therapies: the European Society for Medical Oncology Magnitude of Clinical Benefit Scale (ESMO-MCBS). Annal Oncol 2015;26(8):1547-73.

39. Institut National de Cancer. Étude sur les délais de prise en charge des cancers du sein et du poumon dans plusieurs regions de France en 2011. Available at: http://www.e-cancer.fr/content/download/63265/569429/file/ETUDELSEINPOU12.pdf [Accessed October 2017].

40. ASCO Post. Combination immunotherapy for lung cancer: the wave of the future: a conversation with Naiyer Rizvi, MD. Available at: http://www.ascopost.com/issues/february-25-2017/combination-immunotherapy-for-lung-cancer-the-wave-of-the-future/ [Accessed October 2017].

41. Berger MF, Van Allen EM. Delivering on the promise of precision cancer medicine. Genome Med. 2016; 8:110.

42. American Society for Radiation Oncology. Combination of radiation and immune checkpoint therapy holds potential for lung cancer. Available at: https://www.astro.org/News-and-Publications/News-and-Media-Center/News-Releases/2017/Combination-of-radiation-and-immune-checkpoint-therapy-holds-potential-for-lung-cancer/ [Accessed October 2017].

43. Science Daily. New blood test offers potential for faster, targeted treatment of non-small-cell lung cancer. 2017. Available at: https://www.sciencedaily.com/releases/2017/04/170419091629.htm [Accessed October 2017].

44. Simon AE, Juszczyk D, Smyth N, et al. Knowledge of lung cancer symptoms and risk factors in the U.K.: development of a measure and results from a population-based survey. Thorax. 2012; 67:426-32.

45. Del Ciello A, Franchi P, Contegiacomo A, et al. Missed lung cancer: when, where, and why? Diagn Interv Radiol. 2017;23:118-126..

46. NHS England. Waiting times for suspected and diagnosed cancer patients: 2015-16 annual report. Available at: https://www.england.nhs.uk/statistics/wp-content/uploads/sites/2/2016/06/Cancer-Waiting-Times-Annual-Report-201516-1.pdf [Accessed October 2017].

47. National Cancer Registration and Analysis Service. Cancer survival by stage. Available at: http://www.ncin.org.uk/publications/survival_by_stage [Accessed October 2017].

48. ISD Scotland. Detect cancer early. 2017. Available at: http://www.isdscotland.org/Health-Topics/Cancer/Detect-Cancer-Early/ [Accessed October 2017].

49. Queen's University Belfast. Northern Ireland Cancer Registry. Available at: http://www.qub.ac.uk/research-centres/nicr/CancerInformation/official-statistics/ [Accessed October 2017].

50. International Association for the Study of Lung Cancer. Lung cancer screening and early detection can increase curability and save lives! Available at: https://www.iaslc.org/lung-cancer-screening-and-early-detection-can-increase-curability-and-save-lives [Accessed October 2017]

51. World Health Organization (WHO). Challenges and opportunities in improving access to medicines through efficient public procurement in the WHO European Region. Available at: http://www.euro.who.int/__data/assets/pdf_file/0003/323598/Challenges-opportunities-improving-access-medicines-efficient-public-procurement.pdf?ua=1 [Accessed October 2017].

This doctrine overview was conducted to form a topline review of existing literature on lung cancer (focusing on policy doctrine, as opposed to clinical data) in order to provide an overview of current lung cancer policy strategies in Europe as well as identifying current information/evidence gaps to drive policymaker attention on the need to filling those gaps with enhanced policy interventions.

This doctrine overview was conducted using the following sources, searching for key words including: lung cancer policy/lung cancer AND health economics, cost, stigma, tobacco, policy, inequity, inequality, disparity, women, caregivers, economic burden and social burden.

Sources:

- Association of European Cancer Leagues (ECL)
- Confederation of Family Organisations in the European Union (COFACE)
- Council of Europe (COE)
- International Early Lung Cancer Action Program (I-ELCAP)
- European Alliance for Personalised Medicine (EAPM)
- European Cancer Patient Coalition (ECPC)
- European Commission
- European Federation of Allergy and Airway Diseases Patients' Association (EFA)
- European Institute of Women's Health
- European Lung Foundation
- European Medicines Agency (EMA)
- International Association for the Study of Lung Cancer (IASLC)
- International Cancer Genome Consortium
- European Network for Smoking Prevention (ENSP)
- European Parliament
- Global Lung Cancer Coalition
- Google trends, Google news, Google Scholar
- Health Policy Journal
- International Agency for Research on Cancer (IARC)
- International Union Against Tuberculosis and Lung Diseases
- International Network of Women Against Tobacco
- JSTOR
- Lung Cancer Europe
- OECD e-library
- Organisation for Economic Co-operation and Development (OECD)
- Programme of Action for Cancer Therapy (PACT)
- PubMed
- The Health Effects Institute
- United Nations (UN)
- World Health Organization (WHO)
- Women Against Lung Cancer in Europe (WALCE)
- World Lung Foundation

Overview of word count in main sources*

Source	Lung cancer policy	Lung cancer
Academic databases		
PubMed	1,709	288,391
JSTOR	62,883	18,017
Institutional databases		
UN	876,251	17,489
WHO	1,970	2,720
European Parliament	159	329
European Commission	196	103
Council of the EU	0	0
OECD	306	411
OECD iLibrary	2	38
PAGs databases		
GLCC	11	56
LuCE	3	3

Lung Cancer Europe is formed by people who work passionately to support lung cancer patients and defend their rights, and we are very grateful for all the support we have received from the beginning of our journey, only three years ago.

This report is a reality thanks to the contribution of many people and organizations. We are indebted to all the people who answered our call and completed the survey and responded to our questions as well as the organisations and people who agreed to review this report. We are happy to say that more than 60 people were involved and we want to thank to them for sharing their knowledge and experience with us.

Of course, we would like to thank our sponsors: companies that understood the value of this project and decided to get involved. Thanks to Amgen, Bristol-Myers Squibb, Boehringer Ingelheim, Lilly, Merck, MSD, Novartis, Pfizer and Roche; we appreciate your support and hope to continue working together.

And thanks to all lung cancer patients and relatives, who share with us their experiences, concerns and needs every day. Many of us have been diagnosed with lung cancer or known someone very close to us with this disease, so we know what you are going through. We invite you to count on us, especially if there is something we can help you with. Together we are stronger.

ALONE, WE CAN
DO SO LITTLE
TOGETHER,
WE CAN
DO SO MUCH.

www.lungcancereurope.eu

LuCE is the voice of lung cancer patients, their families and survivors at a European level

luce@etop-eu.org