

THE MELANOMA WHITE PAPER: RESHAPING EU HEALTHCARE FOR MELANOMA PATIENTS:

A PAPER FROM THE
INDEPENDENT COMMUNITY
ADVISORY BOARD (M-ICAB)



EXECUTIVE SUMMARY

Melanoma is on the rise, and is killing thousands of European citizens that could be saved. But saving lives requires European action. Now.

The principal need is for greater collaboration between Member States and across the healthcare sector, including patient representatives, with wider recognition of melanoma as a European healthcare problem, and an agreed approach to tackling it.

At present, effective treatments are lacking, and even where potential treatments exist, getting them to patients is complicated by European and national rules on authorisation, pricing, reimbursement and prescription.

Research is insufficient, and handicapped by inadequate funding, the stringency of data protection rules, lack of coordination, and outdated clinical trial requirements.

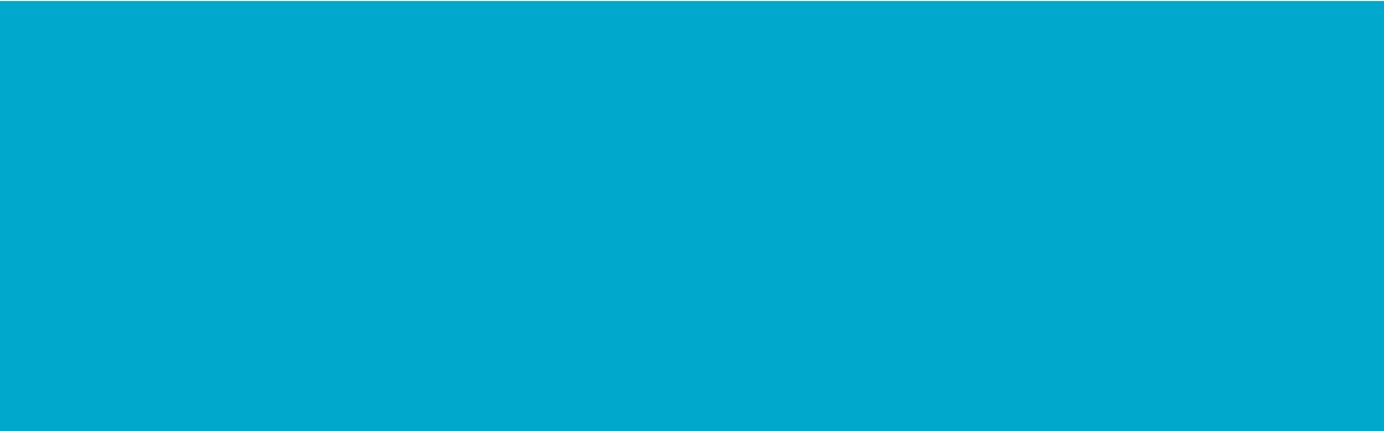
And patients are largely excluded from critical aspects of the discussions on melanoma treatment.

So it is necessary to ease access to innovative treatments - including via better funding, greater recognition of the value to society as a whole of successful treatment, and elimination of inequalities in care.

It is also necessary to boost research - by making the regulatory environment more conducive, by greater cross-border collaboration, and by providing more attractive incentives and facilities for investment,

And patients must be included in melanoma policy formation. They should be formally represented in regulatory and funding organisations, be involved in clinical trial design, and be provided as a right with fuller information about developments in research and treatment. And patients must be given a greater say in their own care.

Efficient and effective action for melanoma patients depends on a coherent European strategy, and a common approach to mobilising and integrating scarce and scattered resources. This white paper sets out the principal actions needed.



FOREWORD

BY

Nessa Childers MEP
& Marisa Matias MEP

As Members of the European Parliament, we know we have a responsibility to the citizens we represent. What this melanoma campaign is helping to raise awareness of is the lamentable fact that so many people die of melanoma every year in Europe - so many of the citizens we represent.

This is why we are anxious to work with this campaign, in a bid to move awareness from the personal to the political level.

The European Parliament has no formal powers of initiative, but it has a strong and growing influence on the environment in which policy is made.

We willingly take on this task of supporting the work of this campaign, to draw attention to the problems, and to help in formulating and clarifying the ideas that can feed into policy to create solutions.

The range of possibilities is broad - and the Parliament has broader powers than before the Lisbon Treaty came into force.

In terms of prevention, we have noted the need for better information to the public, and the call you are already making for a revision of legislation relating to sun cream, sun beds, optical radiation, and sunlight.

In terms of collaboration, the Parliament has repeatedly called for better cross-border and multi-disciplinary cooperation in research programmes. And is already focused on how to make the most of the Horizon 2020 research framework programme, on which it is currently engaged in debates.

In areas of legislation, the Parliament can be a powerful ally. Notably, the upcoming discussions on the new clinical trials rules, or on subjects such as data protection, are of obvious interest to this melanoma campaign.

In terms of funding, too, the Parliament, as part of the EU's budgetary authority, is not without influence on the way that EU money is spent.

But there is a fundamental reality about all political action.

There is only so much that individuals can do, and only so much that individual MEPs can do.

The central recognition that this campaign is making - that greater



collaboration is needed among every stakeholder directly involved in melanoma - is valid too for action in the broader public and political spheres.

Just as it is not sufficient for an individual MEP (or a small group of MEPs) to put down a question or propose a resolution - because without the support of Parliament as a whole, the effect may be limited - similarly, it is not sufficient for individual melanoma patient support groups to operate on their own. The entire melanoma community needs to create mutual support to be effective.

And if the melanoma community is ready to work together with the Parliament, the Parliament will be able to be more effective in this field too, both directly and through influence on other EU institutions.

We are ready to help. We look to the melanoma community to help us to help you.

FOREWORD

BY Patient Representative

Despite the fact that people are dying unnecessarily from melanoma, the disease remains largely ignored in Europe - at national, and, even more so, at European level. It is an appalling waste of lives - with a high economic cost, as well as signifying thousands of personal tragedies for sufferers and their families. Here in Europe, melanoma sufferers lack a cohesive identity or, indeed, any kind of identity. We hardly exist in the eyes of pharmaceutical companies and the European authorities. As a result, melanoma patients suffer doubly: from their disease, and from neglect of their predicament.

Even something as straightforward as registration of melanoma cases is very unequal across the European region. Very few countries have national registries, and where they exist they mostly go back only four or five years.

As a result, patients' access to information is very low in Europe, as is patient advocacy for better standards. It is hard to obtain information about trials, or have access to databases or to policymakers. Yet it is vital - quite literally - that patients have access to trials, too. Efforts should go into improving access to trials, not - as at present - in erecting barriers to prevent patients taking part.

Collaboration is fragmented - among those working in research and industry, and among patient groups. The concern of many

organisations stops at taking care of local needs. This means there is a lot of duplication and unnecessary repetition of processes. We have common needs, but we continue to duplicate the ways we try to address them. There is a lack of an overall perspective, on changing the game. There is a desperate need for systematic thinking, because the gaps and overlaps are apparent right across the spectrum of attitudes to and action against melanoma. Public education and prevention programmes are severely lacking, and where they exist, they are underfunded and short of impact. They need to be bigger, and to be better focused, with campaigns that are designed to target high-risk groups.

Professionals need more information too. Dermatologists – especially in eastern countries – must be educated and encouraged to network to improve their ability to diagnose. Pathologists and general practitioners must be educated as well.

Money is needed for research. National cancer plans need to prioritize funding for treatment. What is most urgently needed is a platform at European level where everyone involved can come together to align their priorities and shape a common agenda. Patients, doctors, dermatologists and other professionals involved are increasingly aware of the need to speak with one clear voice, and to ensure that national patient associations are represented at the European level. Our goals will not be achieved while we are merely acting alone. We need action now.

Because there is a lack of effective treatments. That is unacceptable. And action is needed to remedy that.

And because, even where effective treatments exist, patients often cannot have access to them. This is even more unacceptable. Access is often prevented by mere administrative considerations, such as regulatory issues, delays in reimbursement, and inequalities between member states. It is indefensible that at the same time as the EU is developing its cross-border healthcare directive, there are more and more obstacles to prevent patients from crossing borders to take part in clinical trials.

All of these failings have to be addressed. And quickly. Because for the thousands of melanoma patients who will die unnecessarily if action is not taken, this is not merely an academic debate. It is very directly a matter of life or death.

FOREWORD BY PATIENT REPRESENTATIVE
PROF. PATRICIA GARCIA-PRIETO
PRESIDENT AND FOUNDER OF
MELANOMA INDEPENDENT COMMUNITY ADVISORY BOARD



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Melanoma patients need action at EU level.

Unnecessary deaths of advanced melanoma sufferers could be avoided if there was greater access to prevention, early detection and innovative treatment as well as more efficient organisation of research.

Improvements depend primarily on greater collaboration between Member States and across the healthcare sector, with wider recognition of melanoma as a European healthcare problem, and an agreed approach to tackling it. The collaboration should include patients, caregivers and patient organisations, who have an indispensable contribution to make.

This document aims to increase awareness of the needs. It is a direct appeal to policy-makers, legislators and regulators to encourage innovation and to broaden access to treatment, and to all stakeholders to work more closely together to reduce the burden of melanoma on patients and on society.

MELANOMA IS ON THE RISE, AND IS KILLING EUROPEAN CITIZENS THAT COULD BE SAVED.

Its incidence is rising faster than any other form of cancer, up 237% over the last 30 years (Ries et al., 2003). Best estimates suggest that although melanoma represents only 4% of all cases of skin cancer, it accounts for 75% of all skin-cancer deaths (Miller et al. 2006). Each year in Europe, 62,000 new cases are diagnosed (Ferlay et al., 2007), and more than 20,000 lives could be saved (Globocan, 2008). And these are conservative estimates, since data is still lamentably inadequate at EU level ¹.

Melanoma is a malignant tumour of the cells that produce skin pigmentation. It is triggered by ultra-violet rays, and is particularly common among northern Europeans with frequent exposure to sunlight. Untreated, melanomas can be fatal.

¹ CURRENTLY, THERE IS NO ACCURATE DATA ON SKIN CANCERS AT EU LEVEL AND INCIDENCE RATES ARE PROBABLY UNDERESTIMATED. SUPPORT SHOULD CONTINUE TO INITIATIVES SUCH AS THE EPIDERM PROJECT (AIMING TO ACQUIRE AND DISSEMINATE KNOWLEDGE ON SKIN CANCERS RELATING TO THEIR OCCURRENCE, RISK FACTORS, TREATMENTS AND COSTS OF ILLNESS TO DEVELOP PREVENTION AND RISK REDUCTION STRATEGIES AND BEST PRACTICE RECOMMENDATIONS) AND EUROMELANOMA (A PAN-EUROPEAN CAMPAIGN TO PROMOTE SKIN CANCER PREVENTION THAT PROVIDES FREE SCREENINGS TO THE PUBLIC, AND INFORMATION ABOUT EARLY DIAGNOSIS AND TREATMENT). AS OF 2011, MORE THAN 300,000 PEOPLE HAVE BEEN SCREENED.

PREVENTION CAN DO A LOT.

More effort is needed in prevention. Public awareness of the disease and the risk factors should be developed, particularly among younger people and people with fairer skin, who constitute the groups most at risk. The Euro melanoma campaign, which promotes prevention and provides free screening to the public, is a useful start.



“An early diagnosis makes the disease nearly at 100 % curable. One should support education at all the levels (age, socio economic, in all Europe) to escape from a killing disease “

Prof Veronique Del Marmol (Euromelanoma Europe Chair)

BUT THE DISEASE STILL CLAIMS VICTIMS.

Many patients presenting with early-stage melanoma can be cured with surgery. But for one in five, this is no solution (Ravel et al. 2006). They develop metastatic disease, and the median survival for them is between six and nine months (Chin et al, 2006).

In Scotland and Sweden, five-year survival rates for melanoma patients across all stages of disease exceed 90 percent, but we should note that rates are much lower in Northern Ireland (53.5%), Poland (55.8%), the Czech Republic (60.3%) and Slovenia (60.6%), and many countries in central and eastern Europe face particular challenges in limited physician numbers and cancer registry data, low public awareness, and insufficient education campaigns (Euromelanoma, 2010).

ADVANCED MELANOMA IS CURRENTLY INCURABLE, AND THERE IS NO WIDELY ACCEPTED STANDARD OF CARE.

Until the recent EMA approvals of Yervoy (2011) and Zelboraf (2012), there were no drugs to treat it effectively. Even today, the drugs approved show limited impact on overall survival, with responses limited in number and/or in duration. A significant unmet need remains. It is urgent to develop more effective single and combination therapies that significantly shift survival curves.

THE DISEASE CARRIES HIGH COSTS.

Because advanced melanoma disproportionately affects younger people in their most productive years, an individual who dies from melanoma loses 20.4 years of potential life on average, compared with 16.6 years for all malignant cancers (Ekwueme et al. 2011). The estimated annual productivity loss attributed to melanoma mortality in the US for 2000-2006 was \$3.5 billion (Guy & Ekwueme, 2011). This means an individual who died from melanoma (and his/her dependents) would lose an average of \$413,370 in forgone lifetime earnings. This estimate

of lost earnings as a result of death excludes the costs of medical treatment or loss of income during illness (Ekwueme et al. 2011).

BUT EXTENDING LIFE NEED NOT RAISE COSTS.

A recent study across UK, Italy and France found that though the total health care costs are generally higher for long-term melanoma survivors, the monthly per-patient costs tended to be lower for long-term survivors. Importantly this result suggests that health care resource utilisation and costs do not necessarily increase proportionally when extending survival of advanced melanoma patients (Johnston et al. 2012).

HOWEVER, THE INNOVATION REQUIRED TO COMBAT MELANOMA FACES SERIOUS BARRIERS.

Differing and often conflicting demands are made by the agencies and individuals involved in the approval, reimbursement and uptake of new drugs - regulators, bodies responsible for health technology assessment and reimbursement, payers, and doctors. The EU's Cross-Border Healthcare Directive is highlighting inequalities in patient access from country to country. Sometimes these result from inadequate national budgets, so patients are deprived of new treatments for reasons of finance. Sometimes Member States refuse to reimburse duly authorised products; sometimes they discourage their prescription in first-line therapy, and sometimes the products are excluded from regional formularies.

Even where potential treatments exist, getting them to patients is complicated.

Member States frequently take longer than permitted by EU legislation to make decisions on pricing and reimbursement - from a few months to several years ² - and current economic stresses are intensifying the trend, reducing still further the transparency that there should be in pricing and reimbursement of melanoma treatments ³.



² EUROPEAN COMMISSION (2008) PHARMACEUTICAL SECTOR INQUIRY PRELIMINARY REPORT. BRUSSELS, DG COMPETITION, PP.390-400.

³ SEE PARLIAMENTARY QUESTION FOR WRITTEN ANSWER E-007654/2012 TO THE COMMISSION RULE 117 PETRU CONSTANTIN LUHAN (PPE) IN ANNEX 1

The true value of potential treatments is too often ignored

The diverse methods of deciding prices and reimbursement across the Member States often fail to capture or reward the potential value of a new medicine appropriately. They may underestimate the true value of a melanoma treatment package, for instance ignoring the impact of non-treatment, or the benefits of shortened hospitalisation or reduced side-effects. Insufficient coordination with the processes for authorising, pricing or reimbursement of diagnostics further complicates access to molecular testing and innovative treatments.

Judgements made by authorities on the effectiveness of a therapy are usually based only on clinical trial results, and take insufficient account of the real-world impact at the level of the patient. Data on population-based results is currently insufficient, hampering understanding of the true value of therapies.

Research lags far behind needs.

Most melanoma patients' medical needs are not being met, and there is research expertise but limited funding for independent clinical and prevention studies. But research and innovation are handicapped by inadequate funding, the stringency of data protection rules, lack of coordination, and outdated clinical trial requirements. Where national strategies exist, they differ in scope and in the crucial aspect of financing.

Duplication and fragmentation impede melanoma research in Europe, often because researchers, doctors and patients have insufficient information about on-going trials, and it is difficult to recruit adequate numbers of patients to help speed the best new treatments into daily care practice. At present, there are many obstacles to patients crossing borders to take part in clinical trials. The inadequate EU research infrastructure means that many trials of potential new melanoma treatments currently take place in the US and Australia instead of in Europe.

Current requirements for hundreds of patients and years of data are increasingly problematic in oncology as new drugs become more specific in targeting specific cells expressed in a heterogeneous manner within the same cancer. A homogeneous trial needs to be conducted in a highly selected subgroup of a given melanoma patient population. It is difficult to achieve a sufficient sample size for epidemiological and/or clinical research, or to

assess the feasibility and allow the planning of appropriate trials. Patient care and healthcare planning suffer accordingly.

Current data protection rules in the EU impede the seamless access to medical data that is crucial for both prospective and retrospective medical research. The proposed General Data Protection Regulation threatens to limit bio-banks and retrospective clinical research in ways damaging to health.

The regulatory frameworks for medicinal products and in-vitro diagnostics are insufficiently connected, leading to missed opportunities. Predictive assays to personalize treatment are currently insufficient.

Patients are too frequently excluded from critical aspects of the discussions on melanoma treatment –and even when they are invited, they are often marginalised, as the agenda is already fixed by others.

Patients have little voice in clinical trial design.

Patient perspectives on ethics and risk-benefit are largely neglected in the assessment process of clinical trial authorisation applications.

Patients have little or no say in long-term budget planning or in discussions of pricing and reimbursement of melanoma treatments.

There is no centralisation of the wide range of scattered information on melanoma research and treatment, and insufficient cross-EU centres of excellence, making it difficult for patients to make informed choices about treatment options at their stage of disease.

Member States and the EU institutions should act together to overcome the barriers to innovation, including recognising the real value of new treatments and making access to them easier, boosting research across Europe, and including all stakeholders – and particularly patients – in policy formation.





AN AGENDA FOR CHANGE

Easing access to innovative treatments:

1

A problem with all new anticancer agents is related to the lack of information of clinical effectiveness and cost-effectiveness. Estimation of clinical effectiveness and cost-effectiveness is a part of the research (late translational research). Here we need new types of collaborations between academia, industry and health care systems including international research collaboration. Without this information it is difficult for health care systems to prioritize. It is important those patients are able to participate in such research collaborations independent of where they live.

Budget planning is required for advanced stages of melanoma. National cancer plans need to prioritize funding for treatment, based on dialogue between opinion leaders in the medical professions, commercial and academic research, and paying agencies, so that as new treatments become available, patients are not deprived for reasons of finance.

Greater coordination of product assessment is essential to eliminate anomalies in reimbursement and prescription and to achieve greater alignment in access to new melanoma treatments across the EU. Greater transparency and flexibility is needed in pricing and reimbursement of melanoma treatments, with the involvement of all stakeholders – not just researchers, industry, payers and policymakers, but also patients.

The evaluation of the cost and benefit of new melanoma treatments should include a discussion of their value for society. The patient view of value should be given greater weight in assessments, and quality of life measures need to be adapted to reflect real value added by new melanoma treatments as experienced by patients. Better data derived from new mechanisms are needed on long-term population-based results, so as to better understand the true impact and value of therapies, with variations duly documented, published and debated, and outcomes linked to health economy research.

2

Promoting research on melanoma:

The Cross Border Health Care Directive should be implemented rapidly and efficiently to make good its promise of better access to health care for EU citizens and greater cooperation between EU Member States - a promise highly relevant to melanoma patients struggling against scarcity and uneven distribution of resources for diagnosis and care.

The gaps created by differing national reimbursement systems need to be filled. Exploration is needed of imaginative possibilities, such as a European fund similar to the UK Cancer Drugs Fund, or a medicines equity fund for life-threatening diseases within the 2014-2020 framework for EU structural funds, to allow patients from countries where melanoma treatments are not yet available due to austerity or administrative delays to have equal access to treatment as in countries where the medicines are available.

Research into melanoma needs boosting, with platforms for effective collaboration between academia, industry and healthcare systems, better access to limited numbers of trial subjects, and adaptations to clinical trial design and regulations.

Because limited resources and patient numbers make it impossible for research to be conducted in all countries, sharing of knowledge and expertise is vital to attain critical mass of research efforts. A better structure of clinical melanoma research within the EU should create several centres with sufficient resources to attract and perform early trials of new agents. As part of this collaboration, patients should be allowed to take part in clinical trials at EU centres outside their own countries.

Horizon 2020 should allocate long-term funds for research into melanoma, with increased investment in European research centres, and with advanced databases of biological and clinical data and clinical databases for outcomes research ⁴. Patient registries and databases are essential to permit the pooling of data needed to achieve a sufficient sample size for epidemiological and/or clinical research, and the planning of and recruitment for appropriate clinical trials. Regulations need to be adapted to allow more sharing of patient data and biological materials, and this should be taken account of in the revision of the EU Data Protection Directive.

⁴ SEE PARLIAMENTARY QUESTION FOR WRITTEN ANSWER E-007654/2012 TO THE COMMISSION RULE 117 PETRU CONSTANTIN LUHAN (PPE) IN ANNEX 1



Some people experience great benefits from drug trials — but we do not know who they are! If we had biological samples available, we would be able to identify biomarkers for people who do not respond to the drug. Transnational research is not an add-on, it is an absolutely vital part of clinical trials. Biological tissue samples should be compulsory; it is a waste of money not to identify these biomarkers in the long term.

- Julia Newton Bishop, dermatologist (oral presentation at M-ICAB conference 2011)

Improved coordination of clinical trials - and of recruitment – is needed, with better access to information for researchers, doctors and patients. New (perhaps experimental) methodologies for clinical research should be accepted, especially relating to small patient populations.

Providing for coordinated assessment of the clinical trials application in the revision of EU clinical trials rules would make it easier for academic researchers and industry to jointly organise trials for patients with rare conditions.

Academia and industry should be encouraged to cooperate in discovery and validation of pre-treatment predictive biomarkers for the stratification of patients for treatment.

A clear focus on late translational research, particularly into clinical effectiveness, can identify tangible benefits for the health economy in the short- to medium-term.

The upcoming revision of the In-Vitro Diagnostics Directive should ensure compatibility of the regulatory frameworks for medicinal products and in-vitro diagnostics.

A new collaborative infrastructure for molecular pathology/ bioinformatics is needed to develop the predictive assays for targeted personalized medicine.



M-ICAB LAUNCH 2011

Including patients in melanoma policy formation:

3

Empowerment and involvement of patients and patients' organisations would enrich reflection on how to tackle melanoma. They should be allowed to contribute to shaping an adequate comprehensive European response to melanoma, and be given access to the information they need to perform this role.

Patients should be represented formally on regulatory and payer bodies such as the EMA and HTA agencies, committees and organisations drafting treatment guidelines such as ESMO and quality of life measures such as EORTC, and patient surveys collecting data on quality of service or similar information from patients.

The WHO defines patient empowerment as a 'prerequisite for health' and encourages a 'proactive partnership and patient self-care strategy to improve health outcomes and quality of life among the chronically ill'. In this context, melanoma patient organisations are crucial in direct support to individuals living with the disease and in their collective work in improving conditions for current and future melanoma patients.

Patients should be entitled as individuals to a voice in the choice of treatment and care that they are offered.

EU melanoma care without frontiers should be promoted. Patients should have their rights to information respected, with access to centralized information about melanoma services and care nationally and around Europe (preferably in their own language), including about the best possible treatment pathway at different stages of advanced melanoma, and to help them make informed choices about how and where they may be able to enter a trial. Patient information pathways with approved treatments - like those being developed by the NHS in the United Kingdom - should be developed by at EU level, with cross-EU centres of excellence, and national strategies that will drive patients to them (across borders, where appropriate) to ensure that access to best pathways is available to all. Patients should have access to all data from the relevant clinical trials once a medicine is authorised. ECPC's M-ICAB could contribute to this service.

Patients' representatives should be allowed input to discussions of long-term budget planning.

Patients should be included in clinical trial design, from the elaboration of the problem to phase III and IV trials – in collaboration with the EORTC melanoma group, and by inclusion in ethics committees and increased participation in industry and academic research consortiums. The revision of the EU clinical trials rules should help integrate patient perspectives on ethics and risk-benefit into the assessment process of clinical trial authorisation applications.

Efficient and effective action for melanoma patients depends on a coherent European strategy, and a common approach to mobilising and integrating scarce and scattered resources.

Statements of Support

The EORTC melanoma group role within the M-ICAB project
Since the development of modern approaches to research, melanoma has been taken as a model to be successively applied on other pathologies.

Two examples are evidence of this:

1. Melanoma represents a perfect model for secondary prevention. It will cost much less to educate the population on the importance of early diagnosis. At the end, patient survival is the most important.
2. For decades, immunology has taken melanoma as “the” most relevant solid tumor to be studied for the following reasons: a) it is an immunogenic tumor; b) it one of the most difficult tumors to cure, and c) once an effective cure might be developed, the same approach could be applied for different diseases.

As stated in this white paper, we have succeeded to develop two new drugs that have been approved by EMA and available to patients with metastatic and not operable disease. To obtain this result, clinical trials were conducted for years before these drugs came to be approval in EU.

The following considerations are required:

- a) Patients might be offered and benefit from a new drug independently, whether this is within a clinical study or because it is already in the market.
- b) New drugs need to be approved through rigorous studies, but unfortunately the current situation is that phase I and phase II studies are rarely proposed in the EU by pharmaceutical companies. It is mainly phase III studies that are extended also in EU, but in this way, new drugs are proposed to EU patients only after several years compared to other patients.
- c) Once EMA approves a new drug, each EU country has a different approach, which at the end creates a discrepancy from those who live in a country like Germany where a new drug is available in the market a few days after EMA approval, to others where the same drug might not be approved after months if not years.

The future of modern oncology and of medicine in general is probably summarized in few words: communication, education, innovation and sustainability.

To reach these goals only a common game can be played: the EORTC is one of the actors and will certainly be part of the discussion, but we cannot only play the game with our patients.

Statements of Support

A modern approach requires the politicians to be involved, as well as the EU and National regulatory agency representatives. Finally, we can not forget the pharmaceutical companies: they are the first actors, with the patients, as they have the power to conduct expensive research projects with the goal to produce new and more effective drugs- but they also have clearly to look back at their economical return. Marketing aspects cannot only drive this, it must certainly consider the costs sustained, but also the societal factor in which a new drug will be allocated.

In this field the goals of the EORTC are:

- To propose phase I and II studies (which have been generally reduced in EU);
- To create tables for discussion with all the actors involved where new studies might be designed and which new discoveries can be proposed to patients independently from their geographical origin at a sort of "fast track" pathway. Patients in this way would not need to try to find their cure around the world but can stay in their country, where they finally might have the opportunity to be treated with the best available drug/s - both during the experimental phases and shortly after EMA approval. EU patients should be able to access these treatments equally and simultaneously around the different EU Nations without depending on the therapeutical or compassionate use programs, which pharmaceutical companies might not open before the local approval of a specific drug at a national regulatory agency level.



Alessandro Testori, MD
Chairman of the EORTC
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Statements of Support



“Melanoma has gone from being the prototype of untreatable cancer to being the best example of how advances in scientific knowledge can improve patient’s care. Europe cannot afford to fall behind on the timely development of novel therapies for this disease since it takes away treatment options for patients.”

Prof Antoni Ribas

Professor, Department of Medicine, Hematology/Oncology
UCLA Jonsson Comprehensive Cancer Center UCLA



The Melanoma White Paper 2012 is an extremely well written document that tells the story of melanoma patients everywhere. This life threatening disease has promising therapies for the first time in 40 years but patients do not have access. The Melanoma International Foundation joins our sister organization, M-ICAB in urging you to read carefully and save lives by implementing all necessary means for patient access.

Catherine Poole

Melanoma survivor and president and founder of the Melanoma International Foundation - USA
<http://www.melanomainternational.org>

“Living with a malignant melanoma diagnosis already places an enormous burden on patients and their often young families. Having to fight for access for drugs which provide at least some hope represents an avoidable additional burden which no one whose life is suddenly cut short should face.”

Bettina Ryll

Wife of stage IV melanoma patient, carer, and scientist

Statements of Support

"I welcome the suggestions of the melanoma white paper. Patients and physicians must gather to improve public awareness for the patients affected and the opportunities of prevention. The benefit of the new drugs should be available to the European melanoma population. The limitations need in depth research activities in a network of European melanoma centers.

It is my pleasure to support this initiative"

Prof. Dr. Dummer Reinhard

Department of Dermatology,
University Hospital Zurich, Zurich
<http://www.cnz.uzh.ch/Research/RG1/Dummer.html>

This paper is remarkable because it has been produced by patients, when it actually should have come from the professionals several years ago! Congratulations for a fine piece of work which, while charting the alarming rise in melanoma, also offers optimism in the form of new clever medicines, and the hope of more innovative prevention strategies. The professionals must take note, and act, not alone but in full partnership with the patients

Prof Gordon McVie, MD, PhD

ecancer.org and European Institute of Oncology

Save Your Skin Foundation founder and Stage 4 Melanoma survivor Kathy Barnard endorses and supports the Melanoma White Paper initiative. "The Save Your Skin foundation believe the best available therapies should be accessible to Melanoma patients worldwide. The world Melanoma community has been waiting years for a breakthrough in the treatment of metastatic melanoma and we are all seeing progress and now have the hope of surviving this deadly cancer,"

Kathy Barnard

Melanoma stage IV patient,
president and Founder of Save Your Skin - Canada
<http://www.saveyourskin.ca>

Statements of Support

“The Melanoma White Paper provides compelling evidence of the urgent need to include patient perspectives in the decision processes governing the development of new drugs, a top-priority of the Innovative Medicines Initiative, the 2billion public-private partnership between the European Federation of Pharmaceutical industries and the European Union aiming at reconciling industry and society needs for the ultimate benefit of patients.”

Michel Goldman, MD, PhD

Executive Director, Innovative Medicines Initiative (IMI)

M-ICAB have achieved a great deal in a very short space of time. We are all very conscious that all cancer patients and in particular melanoma patients are often in desperate need of collaboration between themselves and regulatory bodies. The formation of M-ICAB has meant that this is now achievable and I am delighted that they have taken this much needed step.

Gillian Nuttall

Lawyer and friend of melanoma patient,
founder of Factor 50 and Melanoma UK
<http://www.factor50.org.uk/>

“Decision-making in health care is frequently overlooking patients’ view by considering it anecdotic where it should be central. This text is no whitepaper written by experts and endorsed by patients, but a text coordinated by patients and endorsed by all other stakeholders. The result is a unique and fully independent initiative with no other interest than saving and improving the lives of patients diagnosed with melanoma, now.”

Dr Gauthier Bouche

Reliable Cancer Therapies
<http://www.reliablecancertherapies.com/who-we-are>

Remembering



Quentin Van Daele, father of 2, M-ICAB co-founder in Belgium
(passed away march 2012)



Photo of Taron Maberry, father of 3, M-ICAB advocate In UK
(passed away feb 2012)

Petr Krecek, father of 1, M-ICAB advocate in Czech Republic
(passed away june 2012)



Peter-Dieter Schoonjans, father of 2, M-ICAB advocate in Sweden
(passed away february 2012)

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ANNEX 1

Register

Subject: Written question on EU budget for developing research on melanoma

Date published: August 31 2012

Please note that this question will be answered within 8 weeks

Question for written answer E-007653/2012 to the Commission Rule 117 Petru Constantin Luhan (PPE)

Subject: EU budget for developing research on melanoma

The EU has already earmarked financial support for research under the Health theme, but no real data or figures for the precise amounts allocated from the EU budget for developing research on melanoma have been published.

Can the Commission specify the precise amount allocated to programmes linked to melanoma under:

- the Seventh Framework Programme for Research and Technological Innovation (FP7);
- the Competitiveness and Innovation Framework Programme (CIP);
- the Structural Funds;
- Horizon 2020;
- the Connecting Europe Facility?

Can the Commission state how this funding is shared out among the Member States, especially in remote and less developed regions?

Subject: Written question on Pricing and reimbursement decisions for medicinal products for melanoma patients

Date published: August 31 2012

Please note that this question will be answered within 8 weeks

ANNEX 1

Question for written answer E-007654/2012 to the Commission Rule 117 Petru Constantin Luhan (PPE)

Subject: Pricing and reimbursement decisions for medicinal products for melanoma patients

Melanoma patients are being denied an approved and effective therapeutic solution due to the delays in pricing and reimbursements procedures at EU level.

In view of the potential significance of innovative medicines for the therapy and treatment of persons with melanoma, and given that Directive 89/105/EEC establishes a centralised procedure for the marketing authorisation of medicinal products in the European Union, will the Commission answer the following questions:

1. What could the Commission do to safeguard the right of patients to obtain therapy with the medicinal products indicated for the treatment of their pathology (in this case, metastatic melanoma) within the EU, in accordance with a marketing authorisation granted by the Commission in the framework of a centralised procedure under Directive 2001/83/EC, when this medicinal product is not available in their Member State?
2. What measures could the EU institutions take on decisions by national authorities which deny patients access to life-saving medicinal products due to procedural delays in pricing and reimbursement decisions?

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ABOUT M-ICAB

As part of its efforts to put patients at the centre of policy- and decision-making in the field of cancer, ECPC Brussels Office in 2010 established a policy platform, offering under-represented cancer communities the opportunity to speak through a patient-led, independent initiative. This new model of connectivity places the cancer patient at the centre while providing a platform for all stakeholders to come together and exchange views and ideas.

The Melanoma Independent Community Advisory Board (M-ICAB), established as the first ICAB in 2010, aims to build true and meaningful partnerships with researchers, clinicians, pharmaceutical companies, EU institutions and regulatory bodies that will shift discourse from focusing on the 'burden of care' to planning for better cancer survivorship, outcomes, access and care.

Members of the M-ICAB include clinical researchers with a scientific background, professionals in the pharmaceutical and healthcare industries, members of the European Parliament and those patient advocates and cancer patients experienced in living with melanoma.

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