EUROPEAN
CANCER
PATIENT
COALITION

Ensuring access to innovative cancer drugs: the role of diagnostics

Alina Comanescu, President of Health for the Community & ECPC Member

CDDF 9th Alpine Conference

EUROPEAN
CANCER
PATIENT
COALITION

Health for the Community

How?

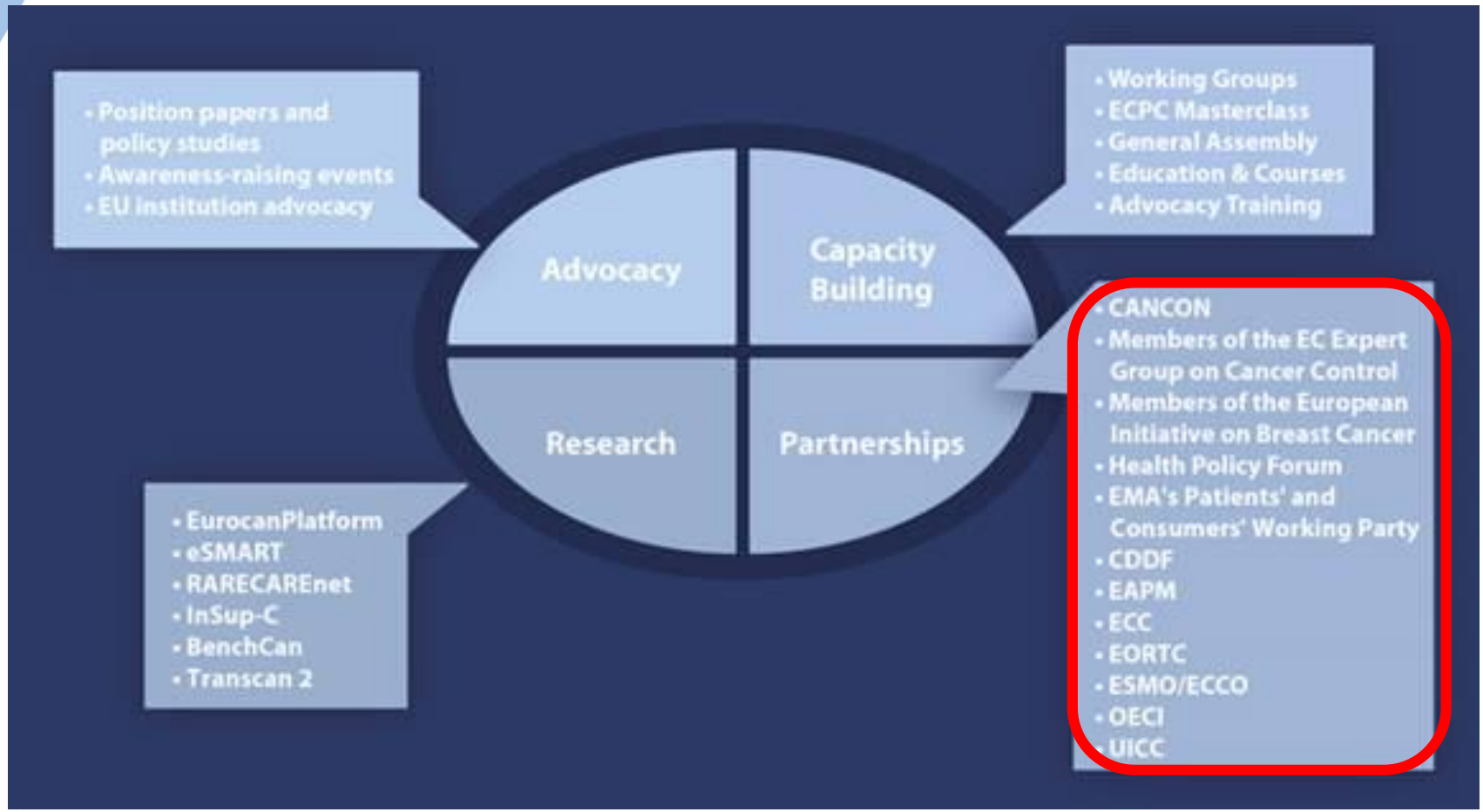
Old thinking	Health for the Community vision
Educational campaign	Social movement involving relevant stakeholders
Complicated patients guidelines	On-line and mobile applications
Almost no cancer support groups	On-line support communities
Found rising campaigns	Crowd funding , young influences & media attention
Early detection is the key of beating cancer	Early detection and lifestyle is the key of beating cancer

ECPC: "Nothing about us, without us"

- **Representing 405 cancer patient groups in 44 countries**
- **All cancer types** – common and rare
- **Run and governed by patients**
- Promoting **timely access** to appropriate prevention, screening, early diagnosis, treatment and care for all cancer patients
- **Reducing disparity** and **inequity** across the EU
- Encouraging the **advance in cancer research & innovation**
- Increasing **cancer patients' influence** over **European health and research policy**

EUROPEAN CANCER PATIENT COALITION

European Cancer Patient Coalition's Activities



EUROPEAN CANCER PATIENT COALITION

ECPC: cancer patients' recognised voice

ECPC represents cancer patients within:

- **European Commission**
  - **Joint Action on Cancer Control – CanCon;**
  - **Joint Action on Rare Cancers**
  - **European Commission's Expert Group on Cancer Control**
  - **European Working Group mHealth apps Assessment Guidelines**
- **European Medicines Agency**
  - **Patients' and Consumers' Working Party**

- ***Memorandum of Understanding with CDDF (2016)***

EUROPEAN CANCER PATIENT COALITION

Access to innovative medicines: a cost & education problem

Survey run in partnership with EAPM:

What do you see as main barriers to the use of innovative cancer medicines?

- Main barrier: High Costs/ lacking financial resources
- Second main barrier: Lack of education and knowledge from both HCPs and patients

EUROPEAN CANCER PATIENT COALITION

The education problem

Patiens and HCPs literacy

EUROPEAN CANCER PATIENT COALITION

Suggestions to improve training on innovative cancer medicines

- **More education**
- As personalized medicine (PM) depends on the disease, **PM should be considered generally in the guidelines of** the respective disease, including possibilities and limitations of diagnostic procedures
- The medical trainee should be exposed **both to diagnostic technology and clinical management** of the patient - this should refer equally to the training of **laboratory specialists** and to **trainees in clinical disciplines, all health care professionals**

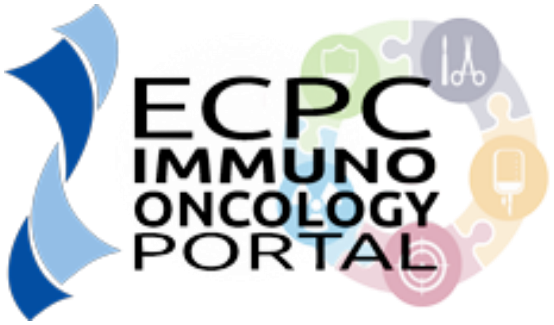
EUROPEAN CANCER PATIENT COALITION

Providing better information to cancer patients
The Immuno-Oncology Portal

- Europe's first **patient-led**, **scientifically validated**, **independent** information portal on cancer immunotherapies and immuno-oncology

- Independently created by ECPC with the support of 6 pharma companies and CDDF

- Content checked by 8 top EU experts on cancer immunotherapies



WWW.IOP.ECPC.ORG

EUROPEAN CANCER PATIENT COALITION

IOP Structure

- **Module on Cancer Immunotherapies**
  - Basic notions to understand the immune system
  - What are cancer immunotherapies?
  - Different categories of cancer immunotherapies available and under the research

- **Module on Immuno-oncology**
  - What is immuno-oncology?
  - Difference between immuno-oncology and cancer immunotherapy
  - How do immuno-oncology treatments work?
- ***Translated in 6 languages (by 2016) + 6 by 2017***

Available now at www.iop.ecpc.org

EUROPEAN CANCER PATIENT COALITION

List of the Expert Group members

Prof Ana Carneiro	Dept. Of Oncology, Skane University Hospital & Lund University	Sweden
Dr Rosa Giuliani	Dept. Of Oncology, Hospital S. Camillo-Forlanini	Italy
Dr Michael Hudecek	Max Eder Research Group ‚T-cell engineering'	Germany
Prof Burçak Karada	Dept. Of Internal Medicine, Ege University	Turkey
Prof Giuseppe Masucci	Dept of Oncology-Pathology, and Karolinska Institute	Sweden
Prof Inge Marie Svane	Dept. Of Clinical Medicine, Herlev Hospital	Sweden
Dr Serpil Tanriverdi-Akhisaroglu	Dept. of Molecular Medicine, Health Science Institute,Dokuz Eylul University	Turkey
Prof Heinz Zwierzina	Head of the Early Clinical Trial Unit, Innsbruck Medical University	Austria

EUROPEAN CANCER PATIENT COALITION

EUROPEAN CANCER PATIENT COALITION

Understanding Cancer Immunotherapy and Immuno-Oncology:

A Guide for Patients

Module 2: Immuno-Oncology Treatments

< PREVIOUS NEXT >

EUROPEAN CANCER PATIENT COALITION

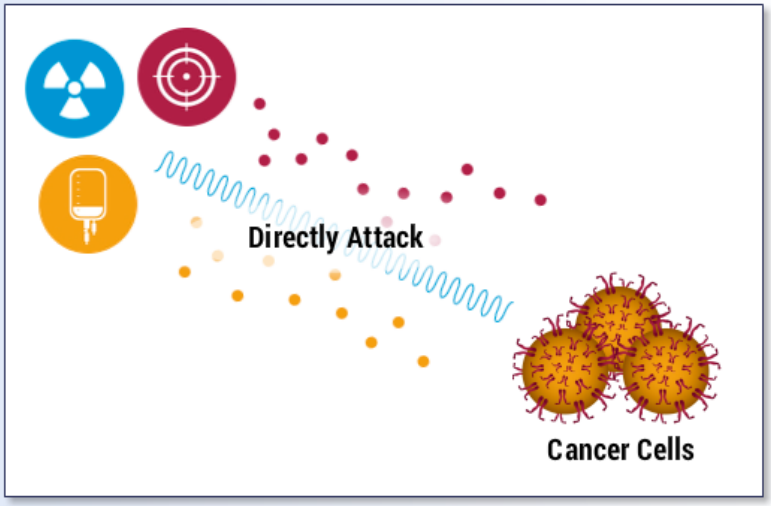
EUROPEAN CANCER PATIENT COALITION

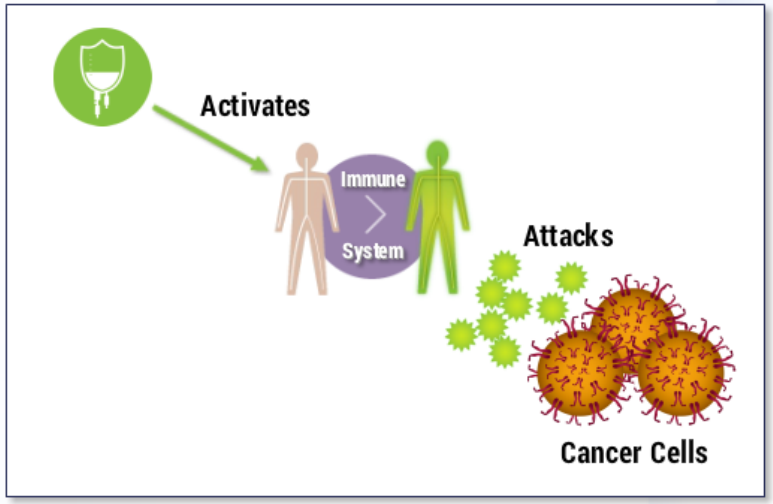
How do immuno-oncology treatments differ from standard cancer therapy?

Immuno-oncology treatments are part of the family of cancer immunotherapies. They **work on the body's immune system** to use its natural mechanisms to attack cancer cells.

Immuno-oncology treatments work differently than standard cancer treatments.

INSTRUCTIONS: Click on the boxes below to see how the treatment types work.





< PREVIOUS

NEXT >

EUROPEAN CANCER PATIENT COALITION

EUROPEAN CANCER PATIENT COALITION

What is immuno-oncology treatment?

How does it work?

How is it different?

What does this mean for you?

Scans may look different for patients receiving immuno-oncology treatment

With some types of immuno-oncology therapy, **there may be a delayed effect** and tumours may only start to shrink after a certain time. This is because immuno-oncology treatments **first act on the immune system**, which then acts on cancer cells.

INSTRUCTIONS: Click on the image below to view how this works.

! Everyone reacts differently to immuno-oncology treatment. Your doctor will be able to explain what the results on each scan or other test mean in terms of how well the drugs are working.

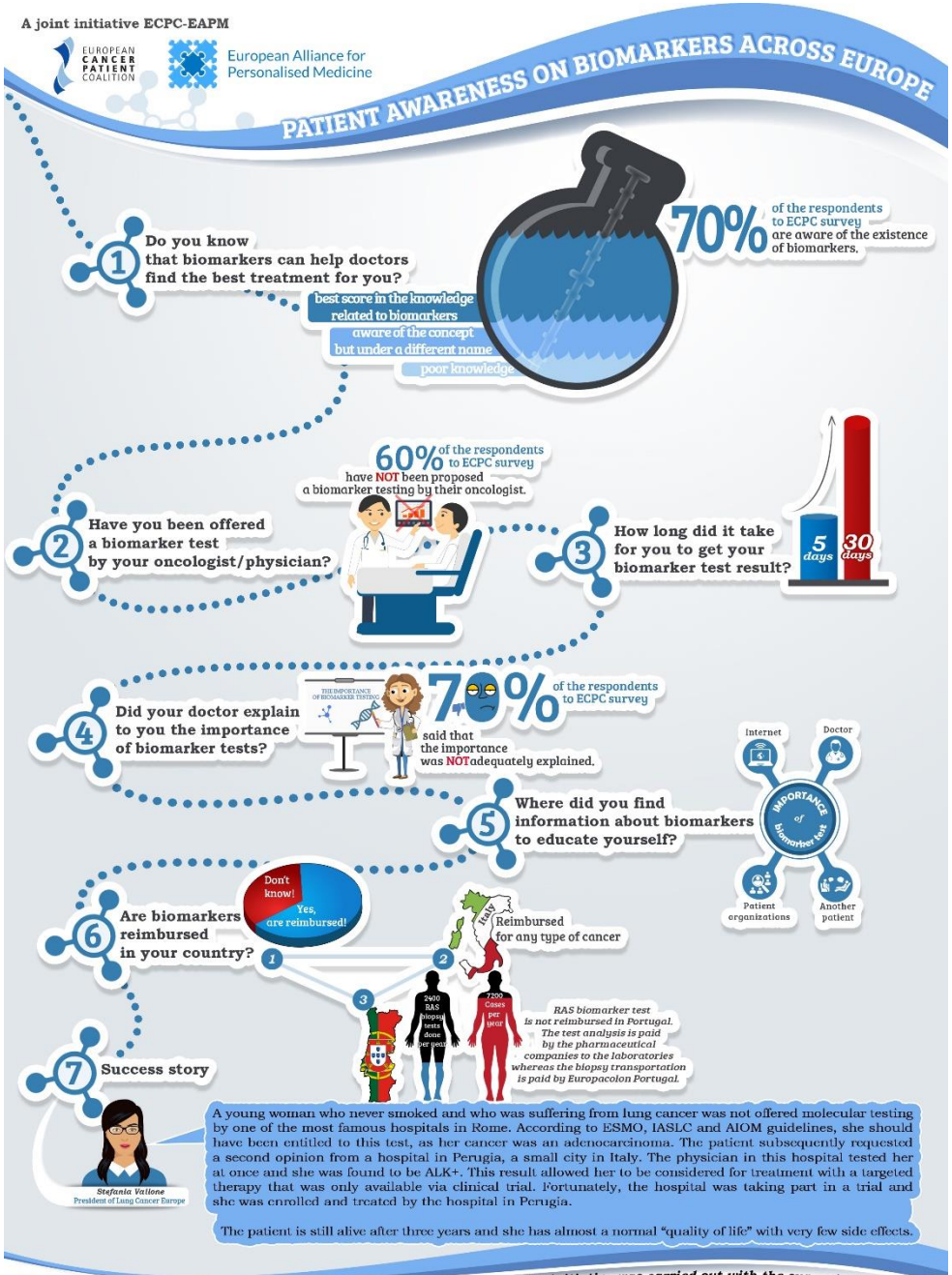
< PREVIOUS NEXT >

EUROPEAN CANCER PATIENT COALITION

Biomarkers awareness campaign:
Making the Institutions understand our position

- **Get Tested Campaign, 24th March 2015**
  - Raising awareness on RAS biomarkers for patients with metastatic colorectal cancer
  - 2016 the campaign will be carried out mainly at national level

EUROPEAN CANCER PATIENT COALITION



EUROPEAN CANCER PATIENT COALITION

A new biomarker campaign in 2017

- Objectives:
  - To improve patient outcomes in oncology
  - To raise public awareness and understanding of the importance of biomarker testing
  - To educate policy makers of the importance of biomarker testing
- Target audiences:
  - EU decision-makers, patient groups and HCPs
- Format
  - Two- hour multi-stakeholder policy workshop/roundtable hosted by **Elisabetta Gardini** and **Lieve Wierinck** in the European Parliament.
  - Social media campaign and dissemination of the ECPC leaflet to our Members

EUROPEAN CANCER PATIENT COALITION

Campaing in Romania in 2017

- More education for the patients!
  - Survey to check patients' literacy on biomarkers
  - Translation of ECPC biomarkers leaflet
  - Campaign on dedicated platform + social media – info on
    - What biomarkers are
    - Biomarkers available
    - Types of cancers that can benefit from biomarkers
    - Special focus on mRAS testing for colon cancer
  - Build a partnership with HCPs at national level
- The broader picture
  - Create a knowledge hub to provide info on innovation to NCD patients thought the Balkans (FYROM, Bulgaria, Romania, Turkey etc…)

EUROPEAN CANCER PATIENT COALITION

The cost problem:

Can cancer patients access innovation?

EUROPEAN CANCER PATIENT COALITION

Patients' paradox

Can we truly access innovative drugs?

ELSEVIER

An exploratory analysis of the factors leading to delays in cancer drug reimbursement in the European Union: The trastuzumab case

Felipe Ades [a], Chistelle Senterre [b], Dimitrios Zardavas [c], Evandro de Azambuja [a], Razvan Popescu [c], Florence Parent [d], Martine Piccart [a,*]

CrossMark

EJC

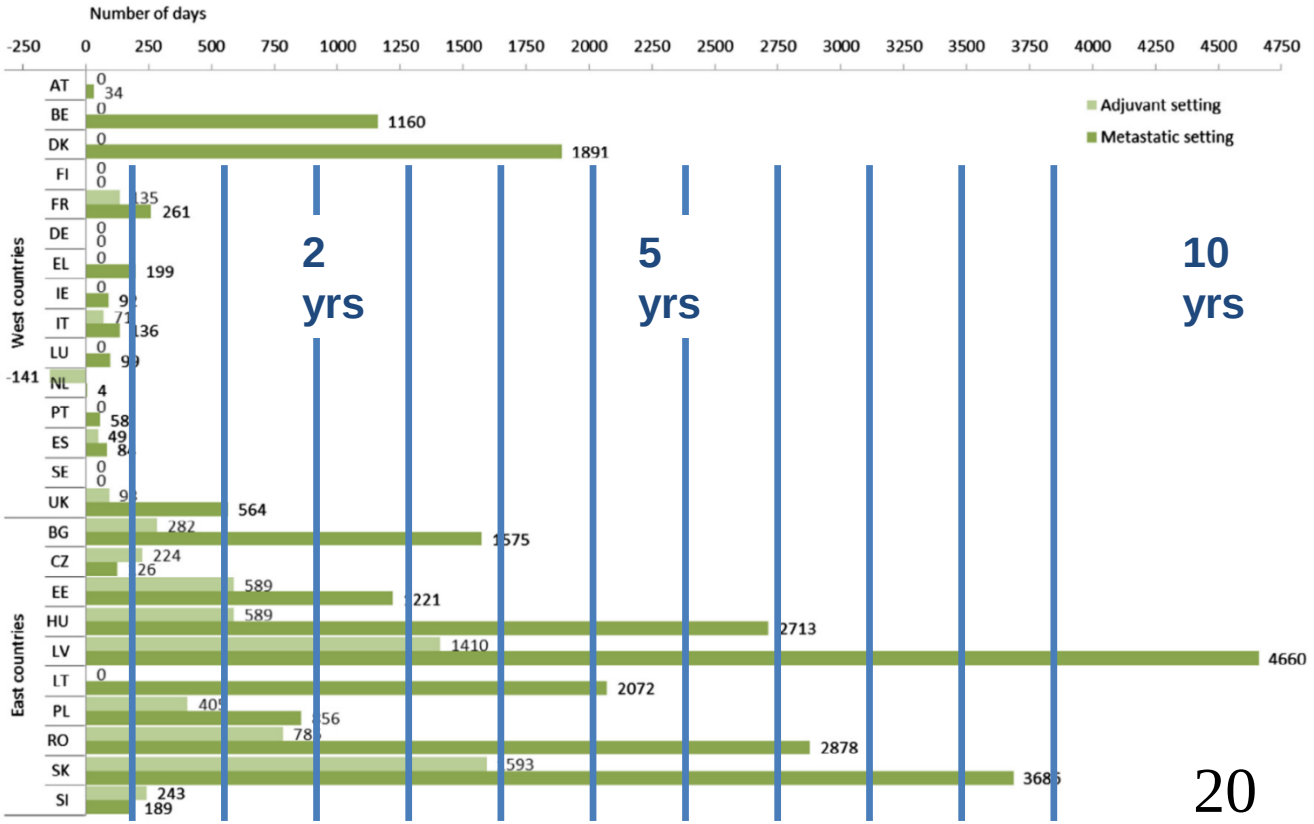
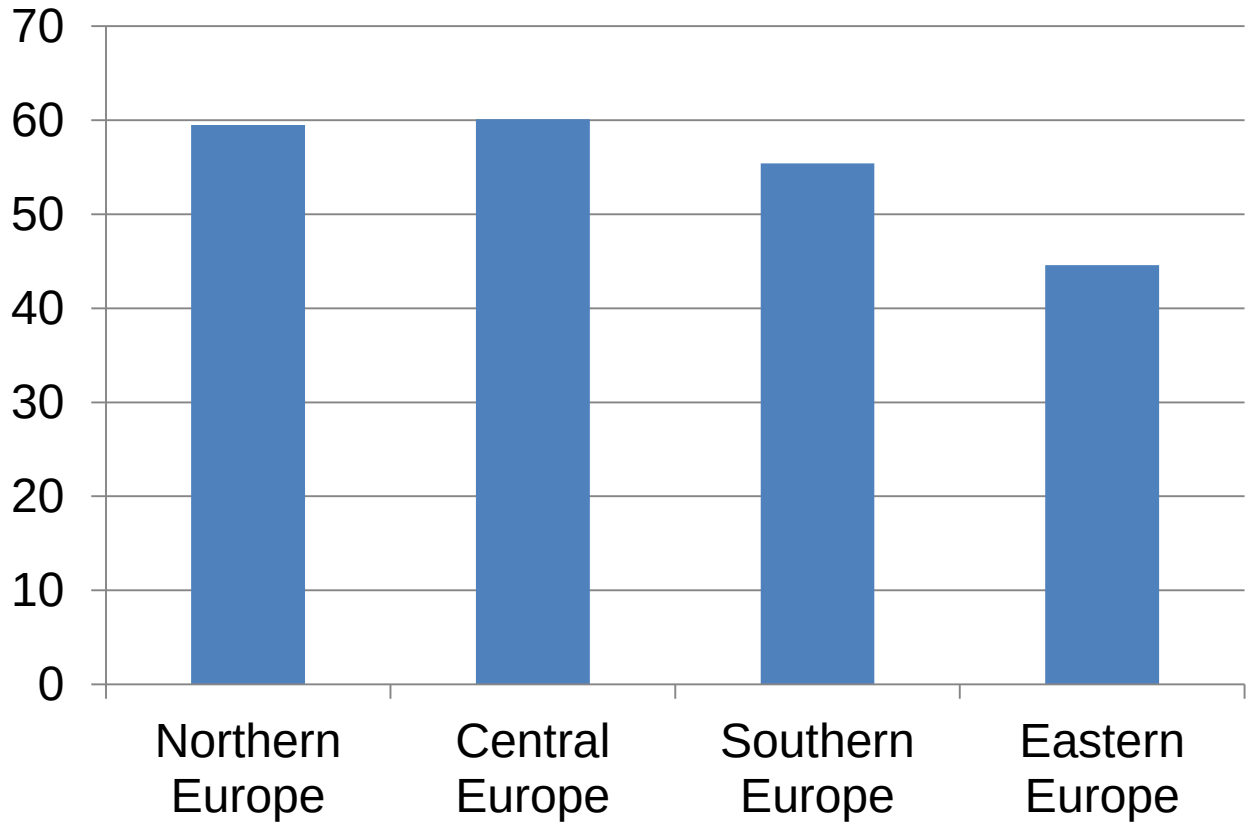


Fig. 1. Time periods for trastuzumab approval/reimbursement in the adjuvant and metastatic settings across European Union (EU) countries.

EUROPEAN CANCER PATIENT COALITION

Inequalities (survival) in cancer care: European reality

The example of colorectal cancer

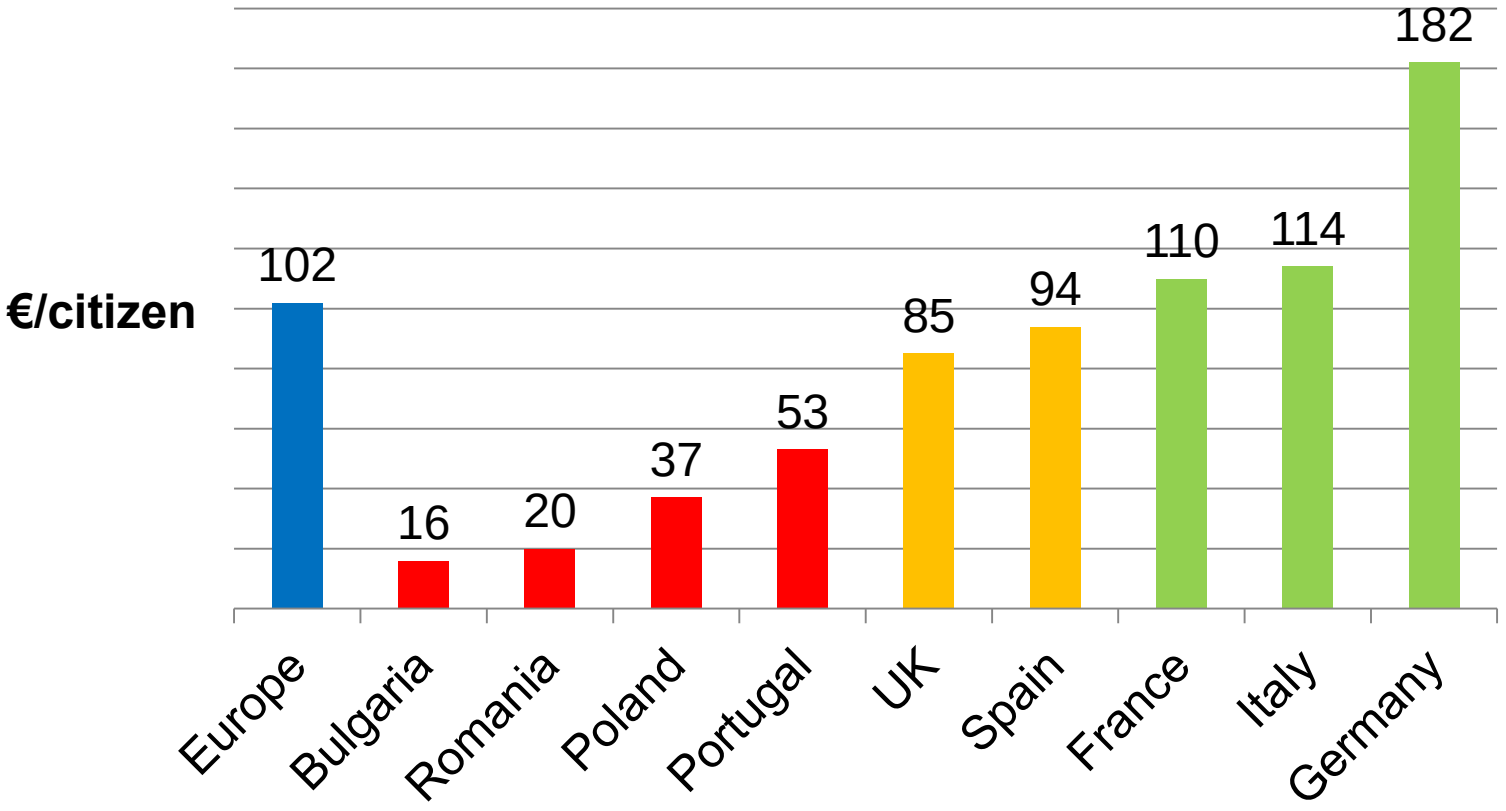


Cancer survival in Europe 1999–2007 by country and age: results of EUROCARE-5—a population-based study, 2013

EUROPEAN CANCER PATIENT COALITION

Inequalities in cancer care: an economic problem

Example: avg. cancer expenditures per citizen in the EU



"Economic burden of cancer across the European Union: a population-based cost analysis." Luengo-Fernandez R1, Leal J, Gray A, Sullivan R., 2013.

EUROPEAN CANCER PATIENT COALITION

Two orders of solutions: EU-level & national level

- EU-level:
  - Promote R&D in biomarkers
  - Speed up marker authorisation of meaningful innovation
  - Harmonise HTA at EU level

- National level:
  - Healthcare expenditures in cancer must match burden of disease
  - Need to train advocates on importance of biomarkers

Patients' questions

Can we truly access innovative drugs?

- Efficacy vs Cost/Effectiveness
  - The EMA evaluates new drugs only on the base of the clinical outcomes;
  - Reimbursement is based on national/regional/local HTA, including
    - Cost/effectiveness
    - Relative efficacy

- Consequences:
  - EMA newly authorised drugs are not timely available to patients by Member States;
  - Reimbursements arrive with huge delays, or at all!

EUROPEAN CANCER PATIENT COALITION

Medicine's Adaptive Pathways for Patients (MAPPS)
A good solution (for some cancers)

- Cancer patients can accept the level of risk related to adaptive pathways.
  However, this cannot become the model for development of all drugs! **MAPPs MUST be linked to clearly defined UNMET CLINICAL NEEDS**
- **Very positive that EMA will involve patients/HTA in MAPPs**
- Communication between regulators-public-patients has to be enhanced: make it BETTER, not just MORE!

EUROPEAN CANCER PATIENT COALITION

Europe of Disparity in Cancer (EoDiC)
ECPC's roadmap to tackle inequalities

- ECPC policy strategy, presented at ECC2015
  - Covers all the inequalities in cancer patients' journey, from early detection to survivorship
- Patient-friendly, scientifically validated recommendations to tackle inequalities in cancer care
- **EoDiC is already making a difference!**
  - CanCon WP5 will use it as a starting point for their policy paper on equity (2016)
  - ***ECPC Recommendations on HTA harmonization included in European Commission's roadmap (September 2016)***

EUROPEAN CANCER PATIENT COALITION

A possible solution:
Harmonize HTA relative assessment at EU level

- EU HTA bodies shall agree to produce one relative efficacy assessment for all Europe
  - This would cut part of the delay in accessing drugs
- Strengthen the collaboration of network of European HTAs within the EMA
  - Institutionalise the EUNetHTA into a new body and formalise its collaboration with EMA
- Start a new debate on pricing and reimbursement policies

EUROPEAN CANCER PATIENT COALITION

ECPC: leverages on European institutions for a solution to delays in access to cancer drugs

- **World Cancer Day 2015 declaration:** 160 MEPs supported ECPC to fight inequalities in cancer care
- **Debate in Plenary, European Parliament September 2015:** MEPs ask the Commissioner for more sustainable healthcare systems & denounced problem of access to innovative treatments
- **Written declaration 30/2015:** ECPC & 19 MEPs ask the European Parliament to take a position on sustainability of healthcare, requesting the Commission to do more to harmonise HTA process at EU level
- **Amendments to the EMA regulation 726/2004:** ECPC supported the amendments to the regulation to pave the way for the EMA to centralise the HTA assessment at the EU level and increase harmonisation

APPROVED BY ENVI - EU PARLIAMENT

EUROPEAN CANCER PATIENT COALITION

ECPC's approved amendments to the EMA Regulation 726/2004

We asked for:

- Overcome the unacceptable delays in access to innovative lifesaving drugs
- Cut inefficiencies, duplications (more than 50 HTA bodies exist today in Europe, working on the same set of data!)
- Produce a legally binding, pan-European relative clinical benefit assessment
- In parallel with EMA evaluation, but produced by a different body (new agency)
- Building on the work done by the Joint Action on HTA – EUnetHTA
- Better inclusion of patients in the HTA process to asses the true meaning of value

EUROPEAN CANCER PATIENT COALITION

From the amendments to the EMA regulation to reality: the Commission Roadmap

- Embraces the recommendations made by ECPC
- Enshrines the existing collaboration
- Provides 5 scenarios for further collaborations
  - 2 scenarios are non-legislative: keeping the *status quo* or mild improvement;
  - **3 scenarios include interventions at legislative level**
    - ***Scenario 3***: aligned HTA methodologies, common templates and tools for national HTA reports
    - ***Scenario 4***: aligned HTA methodologies, common templates and tools for national HTA reports and **joint assessments of the clinical domains of HTA (joint REA)**
    - ***Scenario 5***: aligned HTA methodologies, common templates and tools for national HTA reports and joint assessments of the clinical **and economic domains of HTA (full joint HTA, including cost-effectiveness)**
- **Public consultation to be launched by end of 2016**

Key characteristics	Option 1 The status quo –voluntary cooperation on HTA (until 2020)	Option 2 Long term voluntary cooperation on HTA (beyond 2020)	Option 3 Cooperation on collection, sharing and use of common tools and data	Option 4 Cooperation on the production of joint REA reports	Option 5 Cooperation on the production of joint full HTA reports
Regulatory	Non-legislative	Non-legislative	Legislative	Legislative	Legislative
Participation of HTA bodies and industry	Voluntary	Voluntary	Compulsory (tools) Voluntary (HTA)	Compulsory (tools) Voluntary / compulsory (HTA)	Compulsory (tools) Voluntary / compulsory (HTA)
Uptake joint output	Voluntary	Voluntary	Compulsory for tools	Compulsory for tools and REA	Compulsory
Financing	Largely depending on EU budget Ending 2020	Largely depending on EU budget Long-term	Mixed funding model (EU budget + MS + industry contribution) Long-term	Mixed funding model (EU budget + MS + industry contribution) Long-term	Mixed funding model (EU budget + MS + industry contribution) Long-term
Main joint output					
a. Common Tools/templates	(✓)	(✓)	✓	✓	✓
b. Joint REA	(✓)	(✓)	(✓)	✓	✓
c. Joint Full HTA	(✓)	(✓)	(✓)	(✓)	✓
d. Early Dialogue	(✓)	(✓)	✓	✓	✓

EUROPEAN CANCER PATIENT COALITION

National level solutions

- Issue of delay
  - In Romania we do not have a “Cancer Drug Fund”
  - Access to innovative medicines (reimbursed ones) is SLOW and BUREAUCRATIC
    - 1st: recommendation from the doctor, paired by personal dossier on individual patient (including paediatric cancer patients!!!)
    - 2nd : the dossier is analysed by Romanian MoH (average time: 3 month)
    - Nth: patients re-submit the dossier until eventually the MoH approves it (sometimes after a patient DIES)…
- Issue of accessibility
  - Romania recently established a national HTA
  - Before that, the list of reimbursed drugs was not updated for 7 years!
  - Ground-breaking case brought by cancer patients vs MoH

What we can do together

- CDDF has already been great source of updated and relevant info on cancer immunotherapies
  - Time to work together on biomarkers?
- Patients education
  - Based on the successes of the ECPC Immuno-Oncology Platform
  - Produce together more accurate information on
    - Specific biomarkers
    - Tumour types
- Final objective: raise awareness and educate patients/policymakers

EUROPEAN CANCER PATIENT COALITION

Thank for your attention

email : Alina Comanescu: president.spc@gmail.com
Francesco Florindi: francesco.florindi@ecpc.org

@cancereu

European Cancer Patient Coalition

ECPCtv

Nothing about us without us!

EUROPEAN CANCER PATIENT COALITION