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SESSION 6: HTA ASSESSING RELATIVE EFFICACY

Time for the European reference relative efficacy assessment

CHALLENGES FOR THE APPROVAL OF ANTI-CANCER IMMUNOTHERAPEUTIC DRUGS
London, 5th February 2016

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ECPC: "Nothing about us, without us"

- **Representing 383 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**

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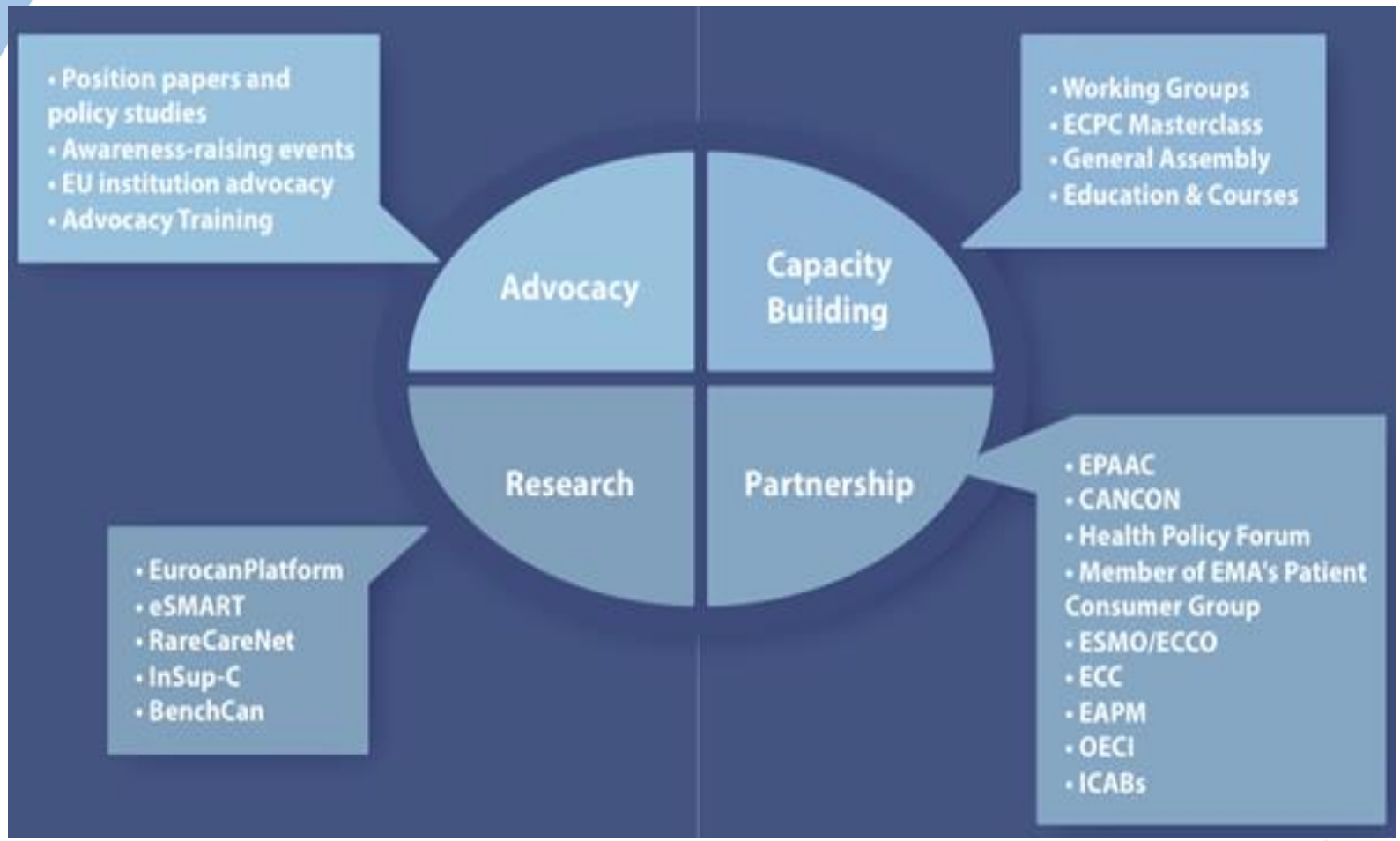
European Cancer Patient Coalition's Activities



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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 Medicines Agency**
  - **Patients' and Consumers' Working Party**

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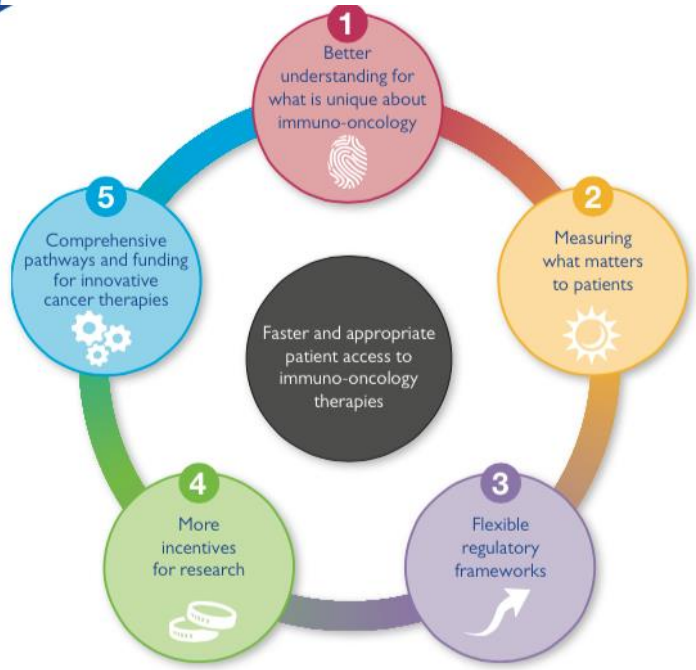
Immuno-Oncology Policy Action Framework
Translating patients needs into policy



- Promote **greater understanding** of what is unique about immuno-oncology – amongst policymakers, regulatory agencies, health professionals and patients
- Ensure that regulatory decisions on the value of immuno-oncology therapies are based on **what matters most to patients:** long-term quality survival
- Ensure **flexibility in regulatory pathways** to provide patients early access to immuno-oncology therapies
- Invest more in **research** to understand how immuno-oncology works for patients **including innovative therapies** in national cancer plans, treatment pathways and funding streams
- **Coordinated by ECPC**
- Developed in partnership with: **ECCO, ESMO, Royal Marsden, CIMT, LuCE, IOD,**
- Launched in November 2014

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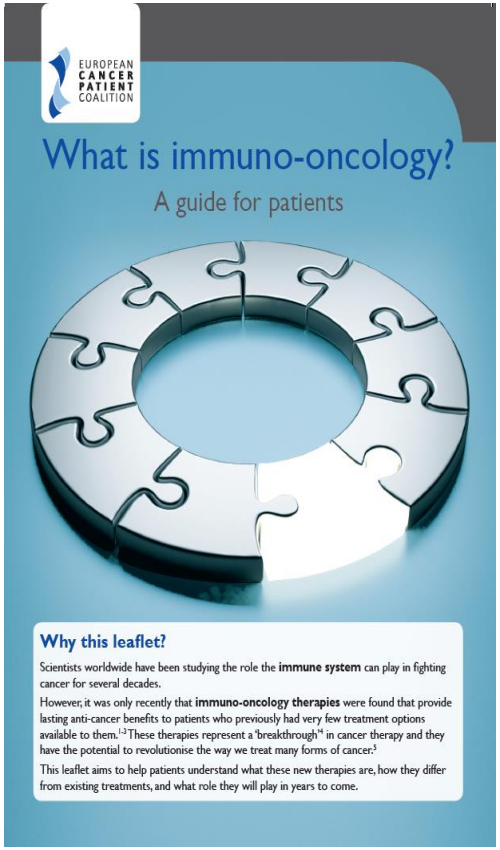
What is Immuno-Oncology
Europe first patient-led info leaflet

Our understanding of how immuno-oncology therapies work is evolving rapidly.

Therefore, patients must have the **accurate, up-to-date information**

- To ensure access of all patients to immuno-oncology therapies;
- To help them have a meaningful dialogue with their doctors;
- To help them understand the role that these therapies may play in their treatment.



Translated in 23 languages

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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

ECPC IMMUNO ONCOLOGY PORTAL

WWW.IOP.ECPC.ORG

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List of the Expert Group members

Prof Ana Carneiro	Dept. Of Oncology, Skane University Hospital & Lund University	Sweden
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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

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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

  To be published in March 2016
- **Module on Immuno-oncology**
  - What is immuno-oncology?
  - Difference between immuno-oncology and cancer immunotherapy
  - How do immuno-oncology treatments work?

  Available now at www.iop.ecpc.org

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Understanding Cancer Immunotherapy and Immuno-Oncology:

A Guide for Patients

Module 2: Immuno-Oncology Treatments

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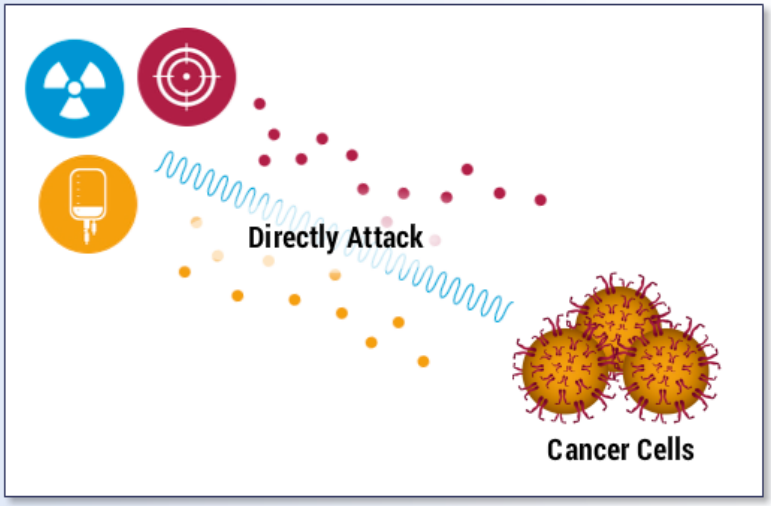
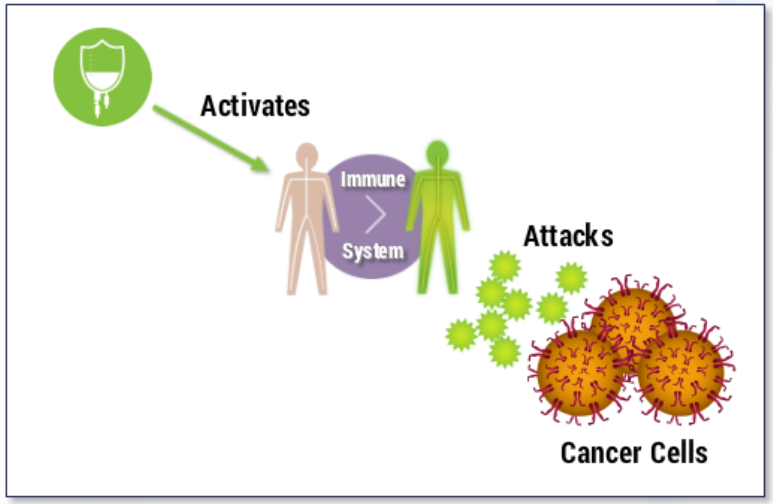
How do immuno-oncology treatments differ from standard cancer therapy?

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.





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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.

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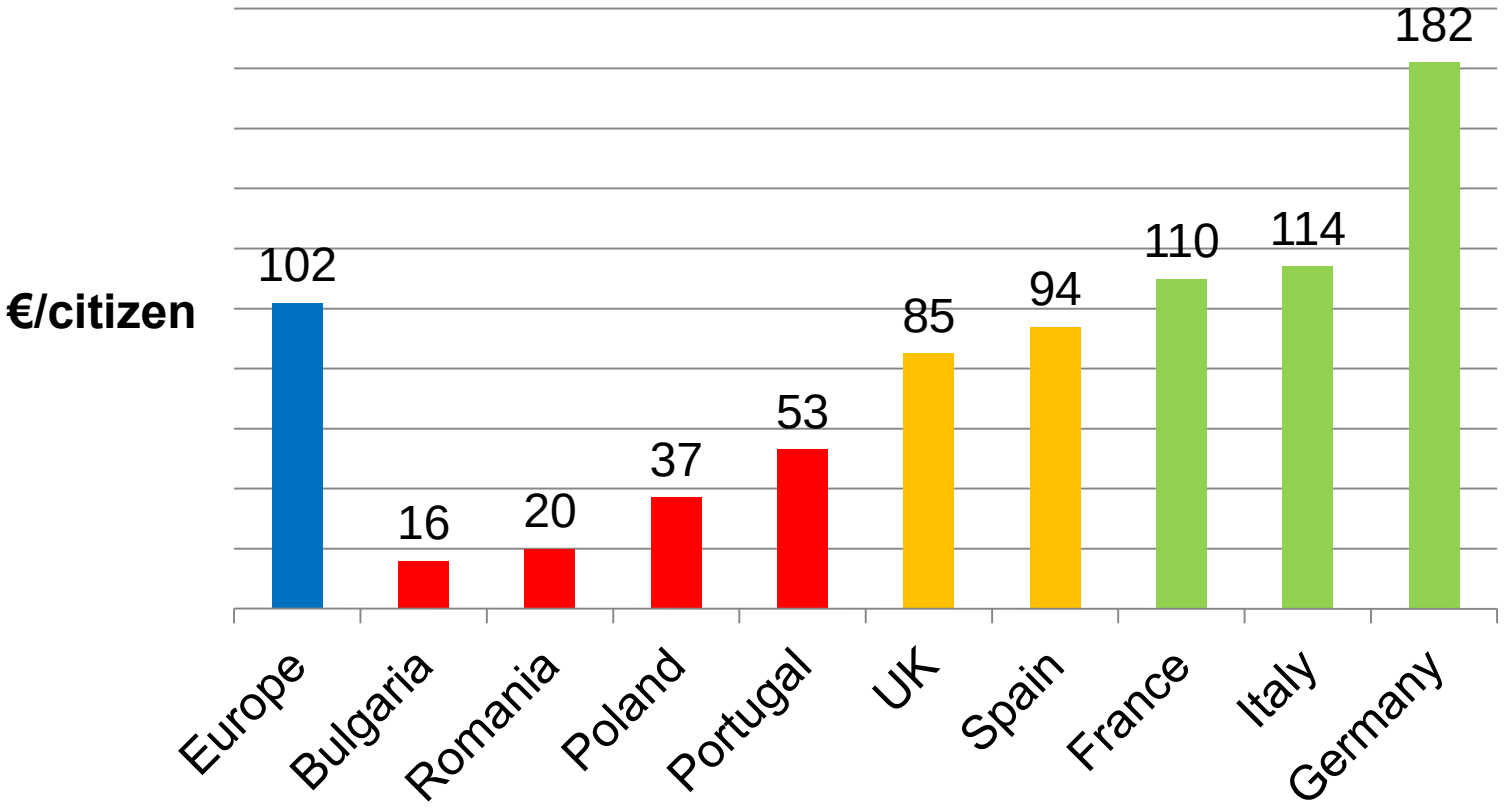
Inequalities in cancer care: an economic problem

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.

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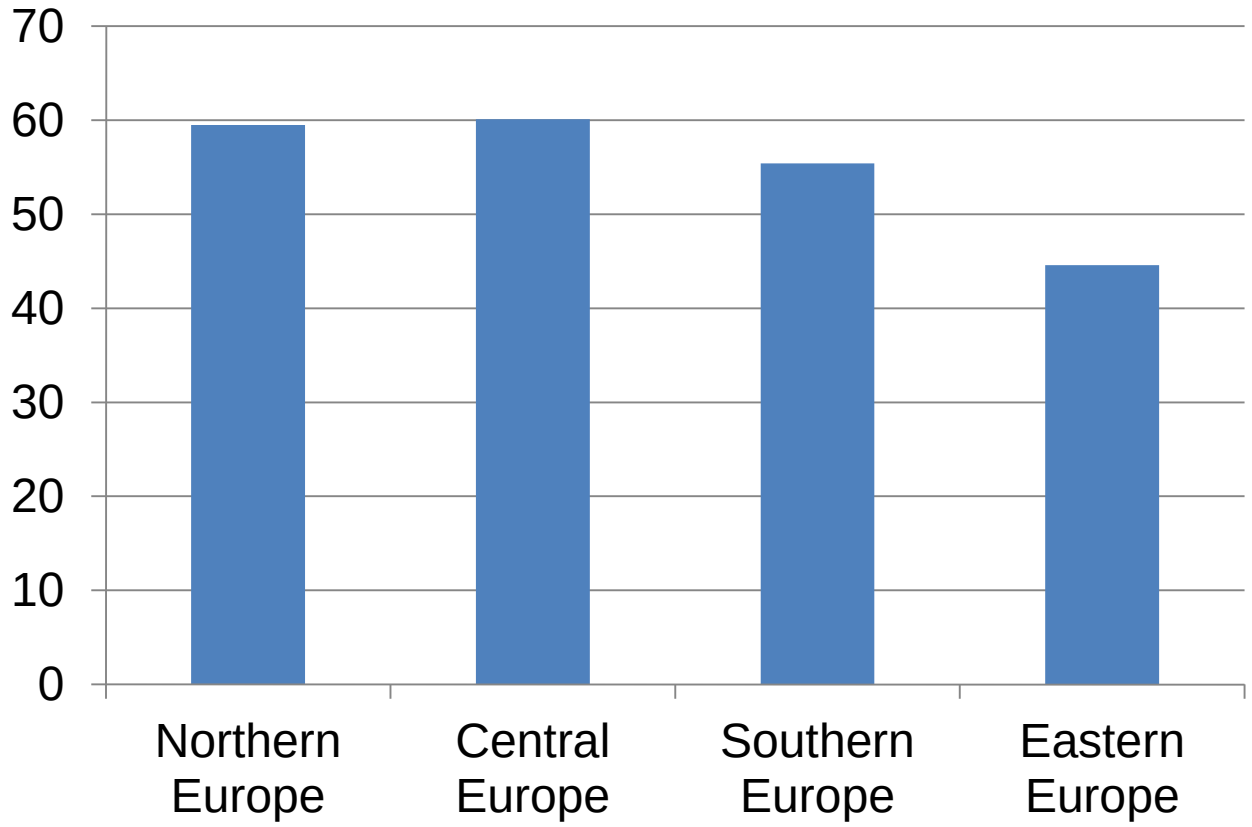
Inequalities (survival) in cancer care: European reality

The example of colorectal cancer



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

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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)
  - EoDiC's principles are at the base of the Written Declaration 30/2015, supported by ECPC and promoted by 19 MEPs

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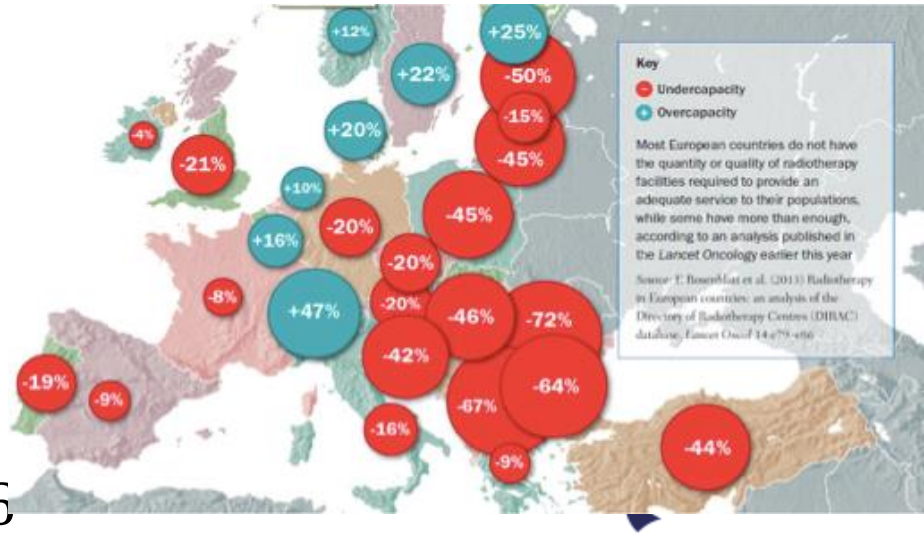
Europe of Disparity in Cancer (EoDiC)

- >50% of European hospital pharmacists have experienced significant shortages in access to life-preserving and life-sustaining cytotoxic regimens
  - In Romania, from 2008 to 2013, over 25 cancer medicines, including essential ones, were either not available or in short supply
- Radiotherapy capacity in Europe:
  - Dramatic under capacity in Eastern EU
  - Problems also in UK, Spain Portugal, Italy



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!

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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,*]

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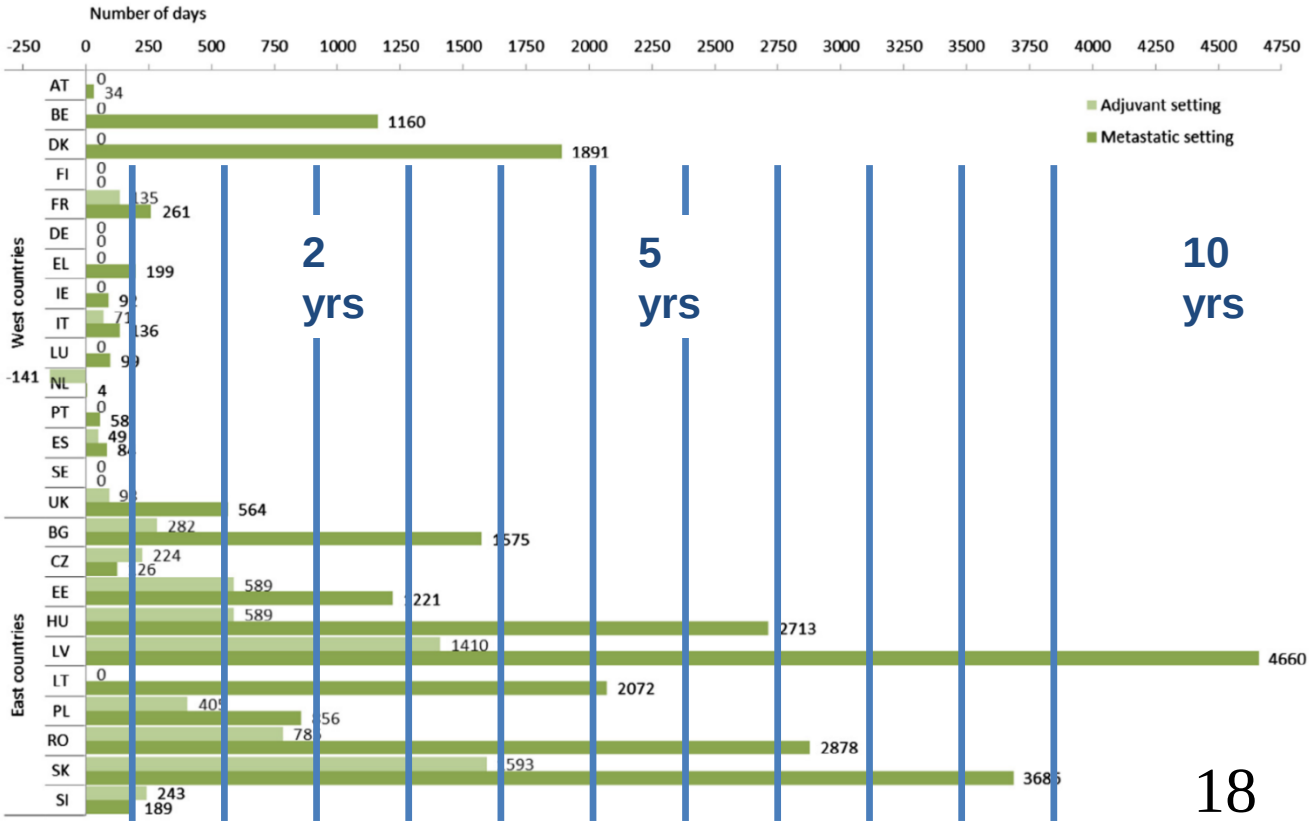

Fig. 1. Time periods for trastuzumab approval/reimbursement in the adjuvant and metastatic settings across European Union (EU) countries.

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Access to innovative drugs: The Italian example

Results of the CENSIS – FAVO – AIOM study

F.A.V.O.
Federazione italiana delle Associazioni di Volontariato in Oncologia

CENSIS

Aiom
Associazione Italiana di Oncologia Medica

Study made on 16 innovative cancer drugs authorised in 2014 and 2015 in 10 Italian regions.

On average, an innovative drugs is available to Italian patients after **630 days from the MA**

- **AIFA: 530 days avg. (min 346, max 934)**
- **Regions: 100 days avg. (min 40, max 170)**

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Access to innovative drugs: The Italian example

The AIFA and Regions behaviour is in contrast with:

- **Transparency Directive 2012/35**: price negotiations can't be longer than 180 days;
- **Italian law 13/09/2012 n. 158:** if a new drugs is **defined as innovative** by AIFA it shall be made immediately available to patients (overruling Regions decisions)
- **Italian law 9/08/2013 n.98**: AIFA **must** evaluate **innovative drugs** within 100 days

This form of reimbursement and cross-evaluations creates a *de facto* RATIONING of innovative medicines

Problem: AIFA definition of innovative drugs is questionable

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Definition of innovation

- **For EMA:**
  "A medicine that contains an active substance or combination of active substances that has not been authorised before."
- **For the European Commission (from Innovation Union):**
  "Innovation means change that speeds up and improves the way we conceive, develop, produce and access new products, industrial processes and services. Changes that create more jobs, improve people's lives and build greener and better societies."

It is necessary to find an European, patient-centered definition of innovative drugs!

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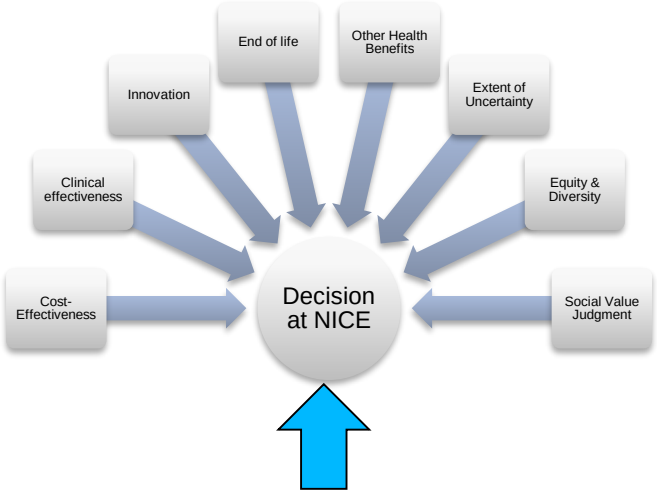
HTA as a tool to ensure faster access
Measuring what matters to patients

- HTA is not a purely technical process, but includes economic, ethical, political and societal aspects
- ***It is necessary to embed patients in all level of HTA, including in EU reference relative efficacy assessment***
- NICE is an example:



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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

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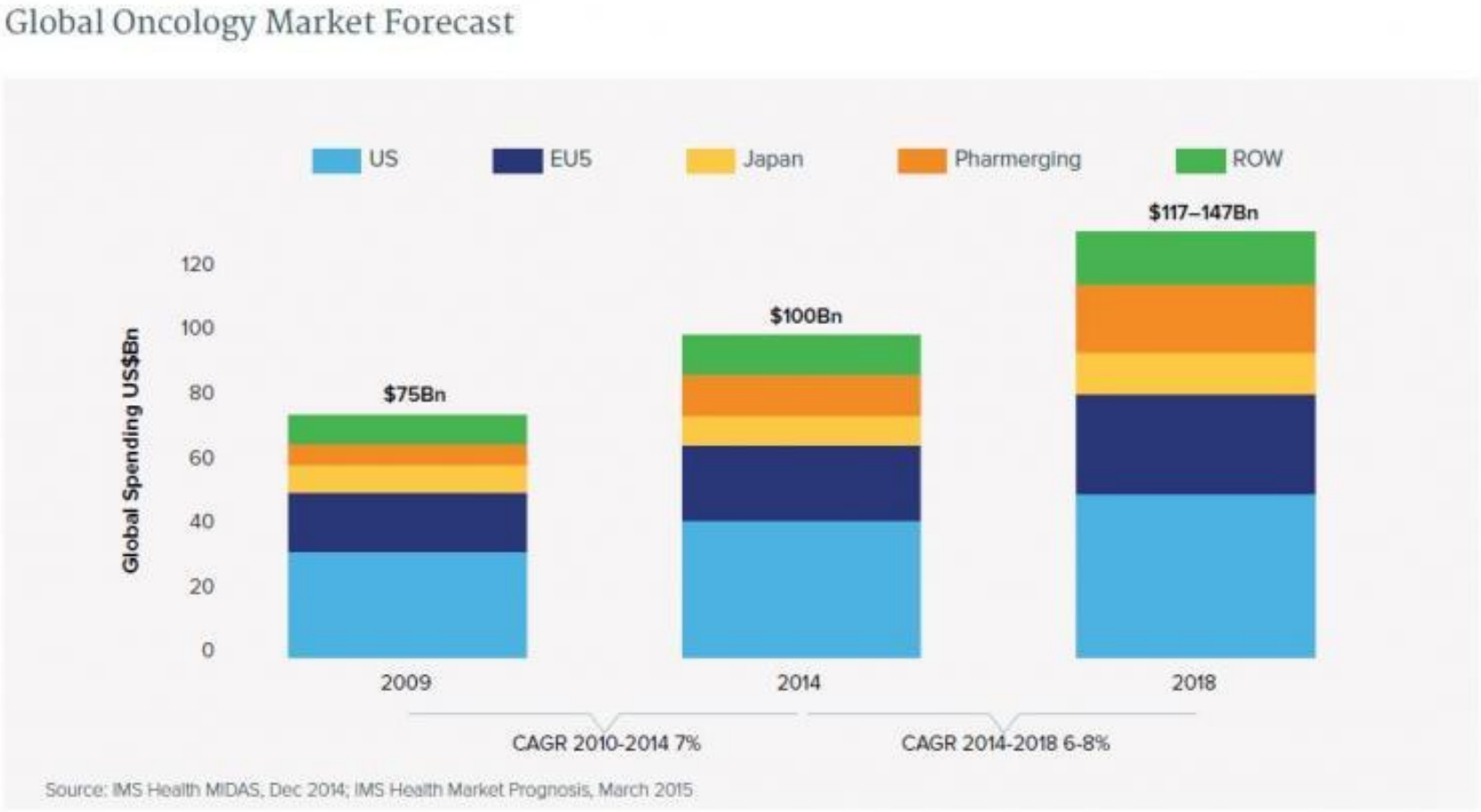
Rising cost of cancer medicines



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Multi-pharma drugs development

Collaboration across pharma can be beneficial to produce new drugs and decrease costs of R&D

One example: Cancer Moonshot 2020 (USA)

- Several stakeholders collaborating (academia, cancer institutes, etc.);
- Several companies signed up to collaborate on the development of cancer immunotherapies;
- Political support from US Vice President

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Adaptive Pathways – 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!

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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

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Legal limits
for EU harmonization of HTA

- **V. Andriukaitis:** “Keen to foster discussions & support cooperation between Member States in these areas (HTA, harmonization of NCP), so as to make medicine more accessible to patients” – Cancer World-Sept. 2015;
- Example of BeNeLux for exchange of information about pricing (France may be joining)
- ECPC welcomes statement of Commissioner Andriukaitis, calling for **a revision of the EU Treaties to give more powers to the EU**

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

We are asking to:

- 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

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Thank for your attention

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European Cancer Patient Coalition

ECPCtv

Nothing about us without us!

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