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COALITION

ECPC triggering change

Our contribution to the revision of Regulation 726/2004

ECPC AGM 2016, Brussels, 4th June 2016

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Our beacon:
European Cancer Patient's Bill of Rights

- **The Bill of Rights:**
  - **A catalyst for change:** to provide every European citizen with the right to the optimum standard of care;
  - Basic tool for all EU cancer patients
  - Wide political support

Launch of the Bill of Rights in Strasbourg, 2014

- **ECPC Call to Action**
  - First **action point** derived from the Bill of Rights
  - A **political manifesto** for the **new MEPs**, engaging them in fighting cancer;
  - More than **25 subscriptions**, from all groups
  - **Objective: creation of first cancer intergroup**

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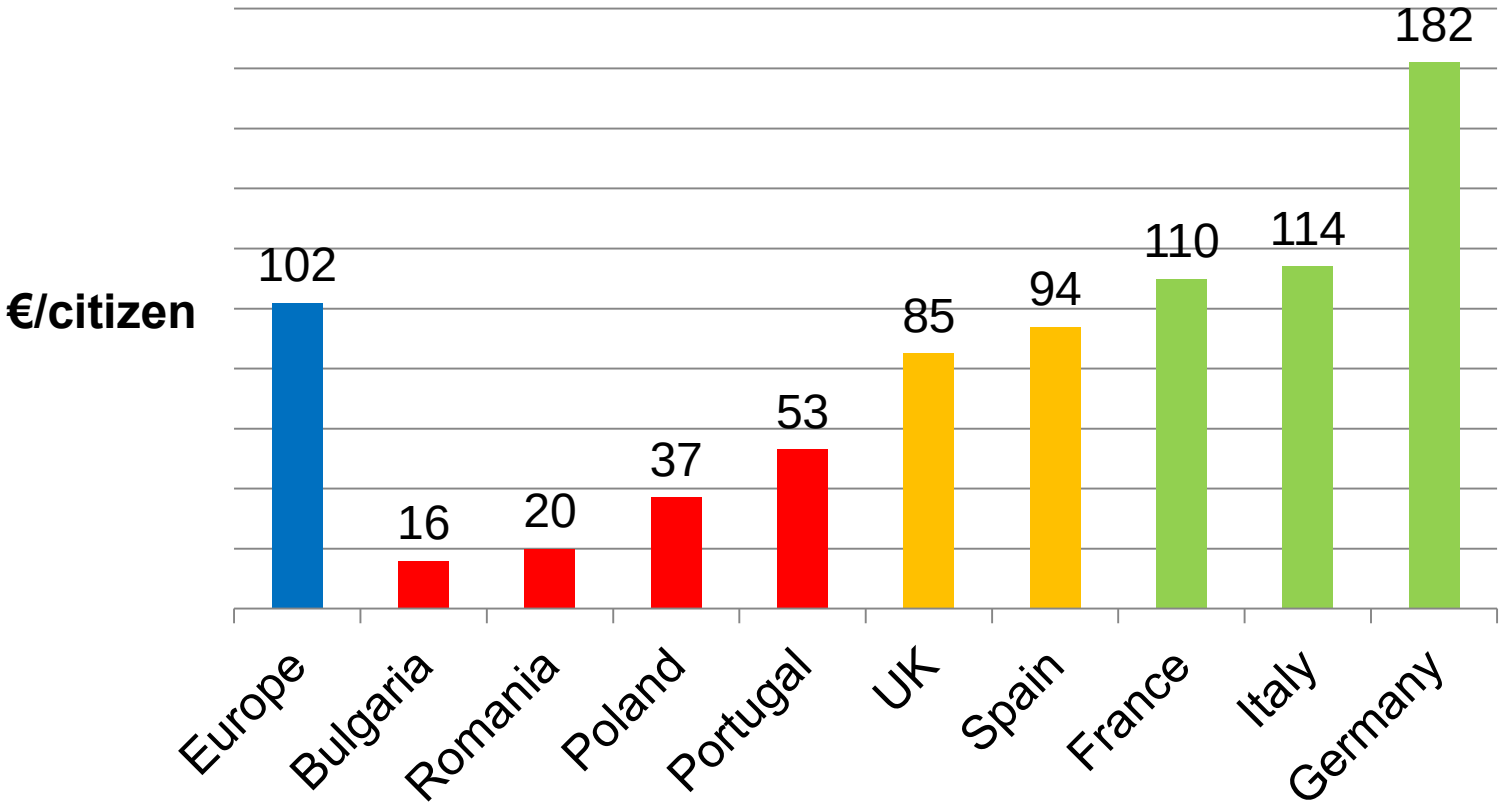
Inequalities in cancer care: a European reality

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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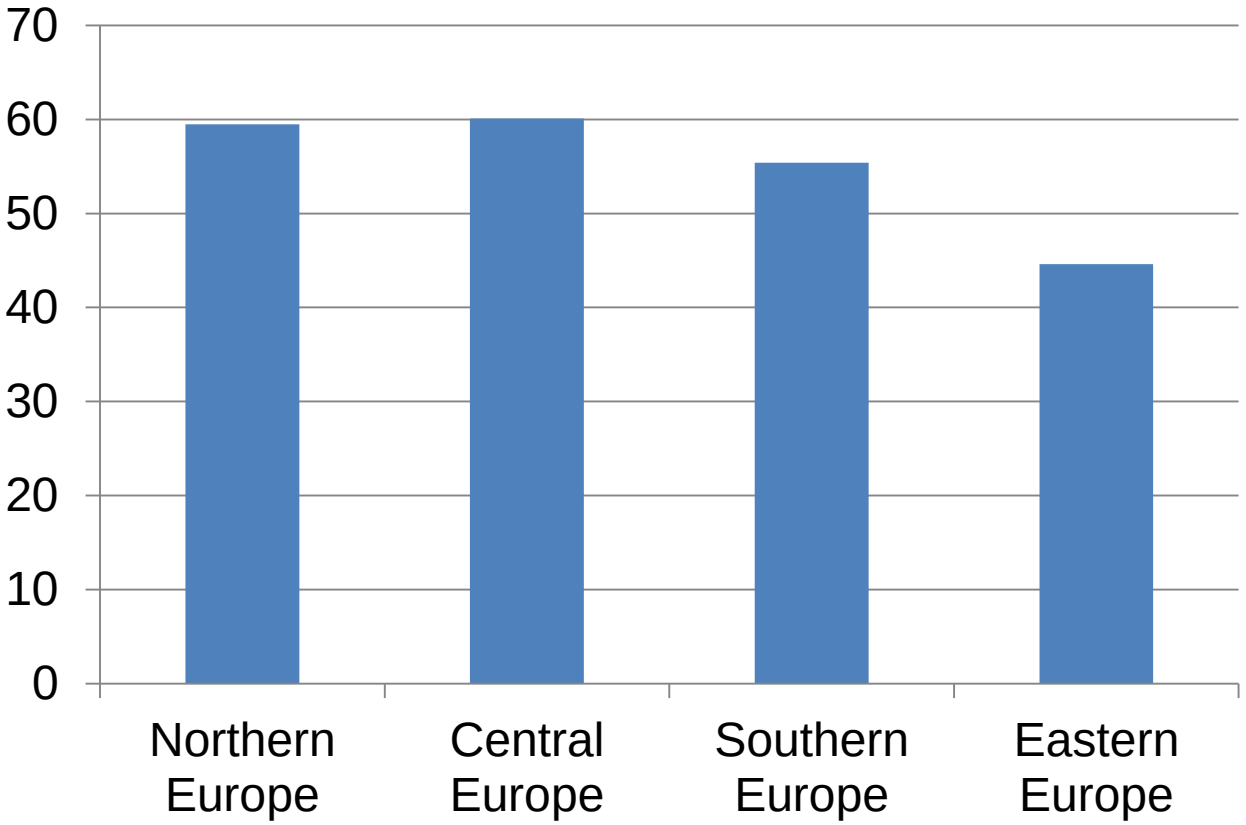
Inequalities in cancer care: a European reality

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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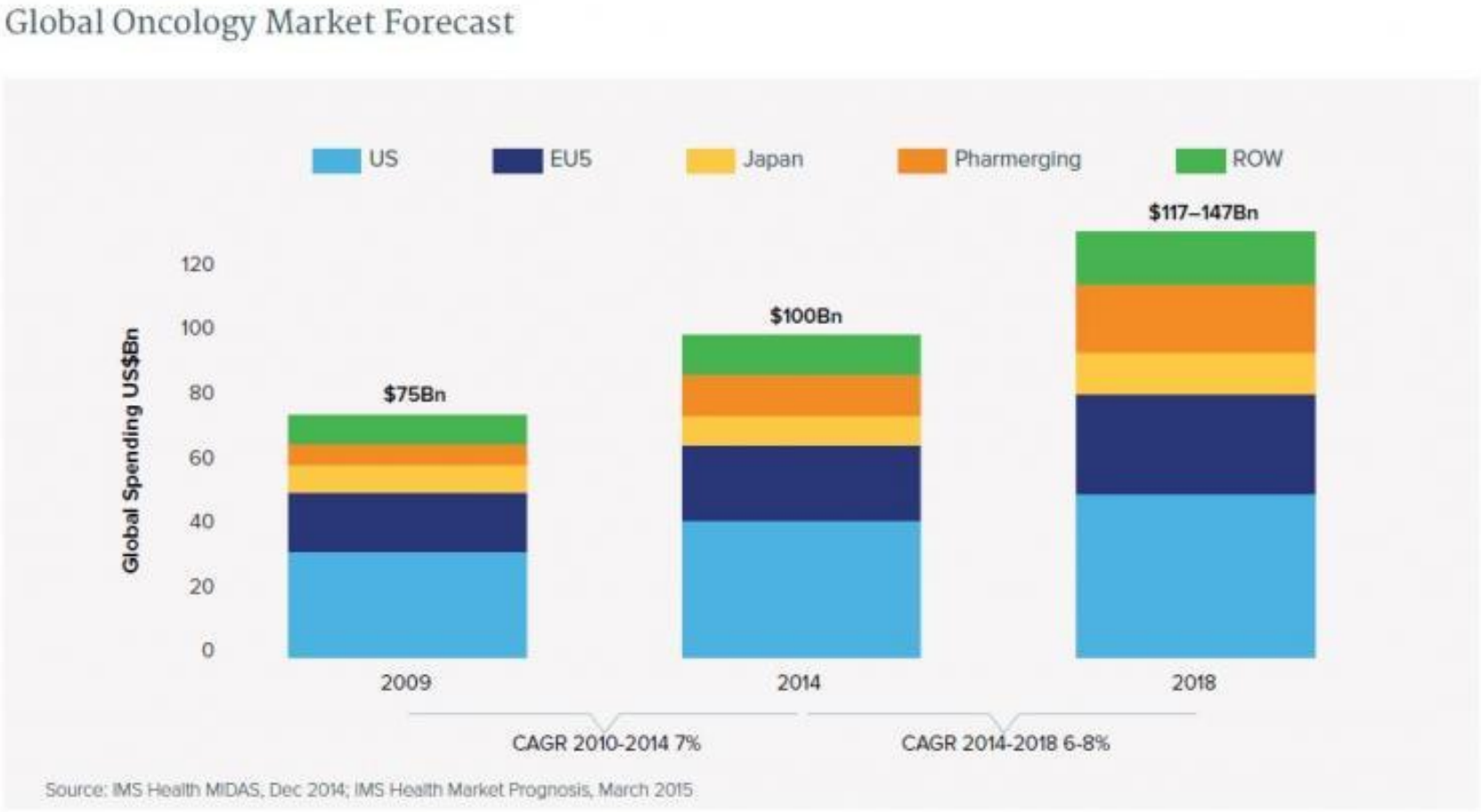
Rising cost of cancer medicines



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Accessing lifesaving innovative drugs

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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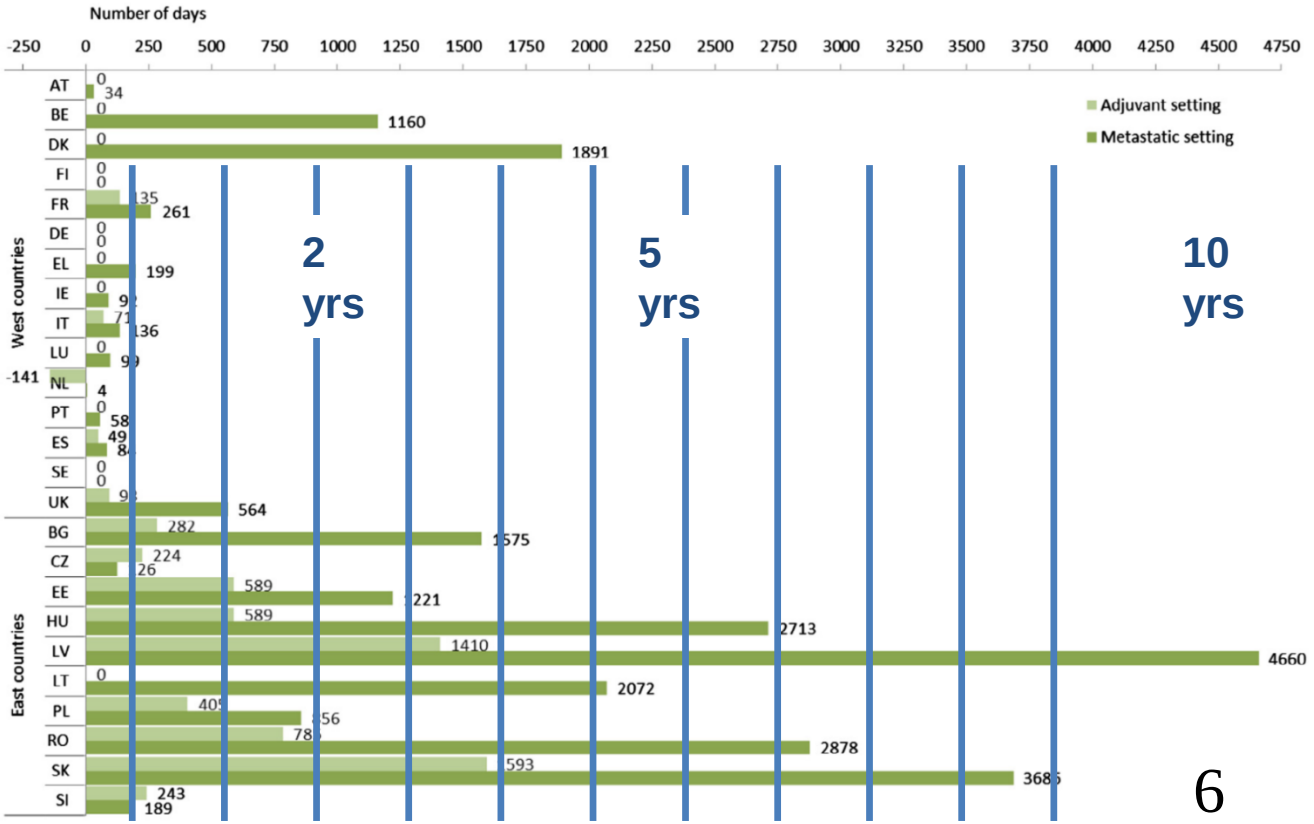

Fig. 1. Time periods for trastuzumab approval/reimbursement in the adjuvant and metastatic settings across European Union (EU) countries.

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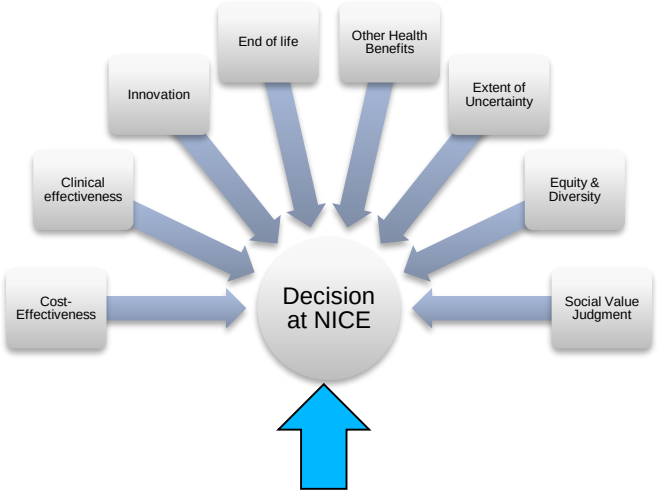
HTA as a tool to ensure faster access
Measuring what matters to patients

- 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:
CUT THE TIME FROM LAB TO BED
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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Europe of Disparities Launch event
European Parliament – 27th January 2015

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

APPROVED BY ENVI - EU PARLIAMENT

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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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