Economic sustainability of melanoma treatments: Regulations, Health Technology Assessment and Market

The point of view of the patient organization

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ECPC: Nothing about us, without us

- **Representing +370 cancer patient groups in 47 countries**
- **All cancers** – common and rare
- **Reducing disparity** and inequity across the EU
- Promoting **timely access** to appropriate prevention, screening, early diagnosis, treatment, care & follow-up for all cancer patients
- Increasing cancer patients' **influence** over European health and **research policy**
- **Run and governed by patients**
- Encouraging the **advance of cancer research & innovation**

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ECPC: cancer patients'recognised voice

- European Commission
  - Joint Action on Cancer Control – CanCon
  - European Commission's Expert Group on Cancer Control
  - European Commission Initiative on Breast Cancer-Quality Assurance Scheme Development Group (ECIBC/QASDG)
- European Medicines Agency
  - Patients' and Consumers' Working Party
  - Health Technology Assessment International
  - Patients and Citizens Involvement Group (HTAi/PCIG)

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Europe of Disparities in Cancer

ECPC policy strategy vs inequalities

Patient-led, scientifically based policy effort

www.ECPC.org

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Europe of Disparities in Cancer

- Main message: there are still vast inequalities in access to quality treatment
  - Radiotherapy
  - Surgery
  - Survivorship and rehabilitation
- Strengthen EUnetHTA
- We need to further harmonise HTAs in Europe to reach EU-wide HTA reference evaluation
- Institutionalise patients' role in HTA bodies
- Enhanced importance to survivorship in HTA evaluation
  - Todaywehave8.5millionsurvivors
  - Many can be considered "cured"
  - HTA MUST take into consideration economic value of survivors

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Radiation Therapy

- Across Europe, around 50% of all cancer patients should receive radiation therapy at some stage during their disease.
- However, despite being a significant part of our arsenal in combatting cancer, a large discrepancy exists between the actual and the optimal utilisation of radiation therapy in Europe.

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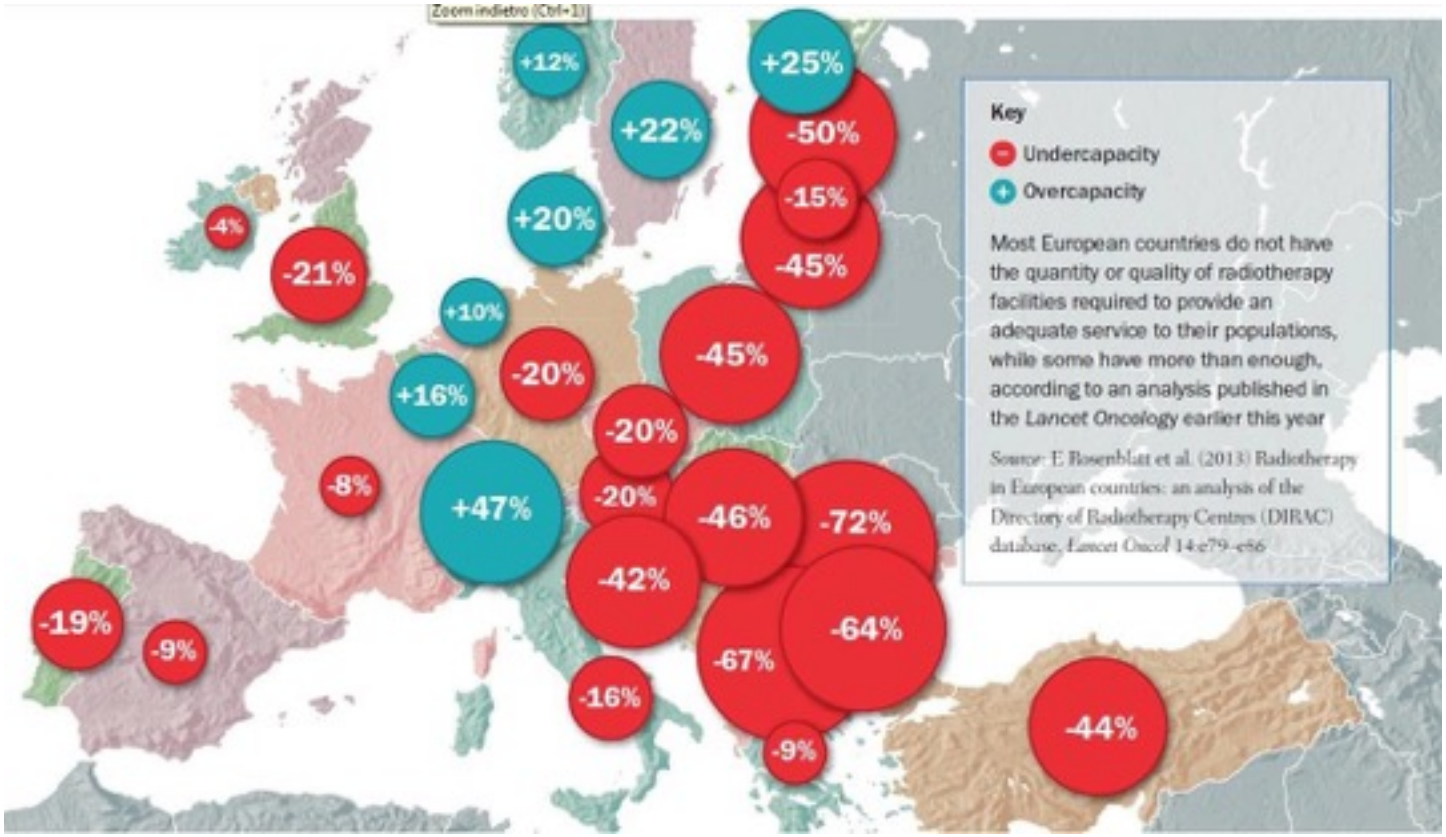
And its not just drugs! Inequality in radiotherapy capacity across Europe



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Radiation oncology capacity

- Significant deficits in access to modern radiotherapy equipment in Europe
- Similar picture when staffing levels are evaluated, thus translating into unequal access to cancer care for European patients
- Deficiencies are experienced not only in Southern and Eastern European countries, but also in Western European countries

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ACCESS TO SURGERY

- Delivery of “standard-of-care” surgery ranges from 9% to 78% across Europe and inequalities are evident, even between countries with medium-to-high expenditure on health
- Delivering surgical care in cancer centres where specialist surgical oncologists perform optimal numbers of procedures with appropriate complexity provides the best opportunity to ensure improved outcomes.

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Best Practice

- Establishing optimal benchmarking standards for surgical oncology at European level, eg EURECCA(EUropean REgistry of Cancer Care), will help reduce the current inequalities experienced by cancer patients,
- Information sources such as the Italian Oncoguida (www.oncoguida.it) provide patients with accurate activity data to aid in their choice of surgical centre and should act as a blueprint for other MS

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We live a Paradox!

- Availability of innovative & effective drugs but not to all patients across the EU
- Unacceptable delays in the reimbursement of new lifesaving drugs across Europe

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Innovative Medicines

- Increased understanding of disease biology is fuelling a “personalised cancer medicine” revolution.
- However, for a drug like transtuzumab, which targets an “out of control” breast cancer gene and has led to a new standard of care, there are marked differences in time to approval/ reimbursement across EU MS, thus accentuating inequalities in access to optimal cancer care

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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,*]

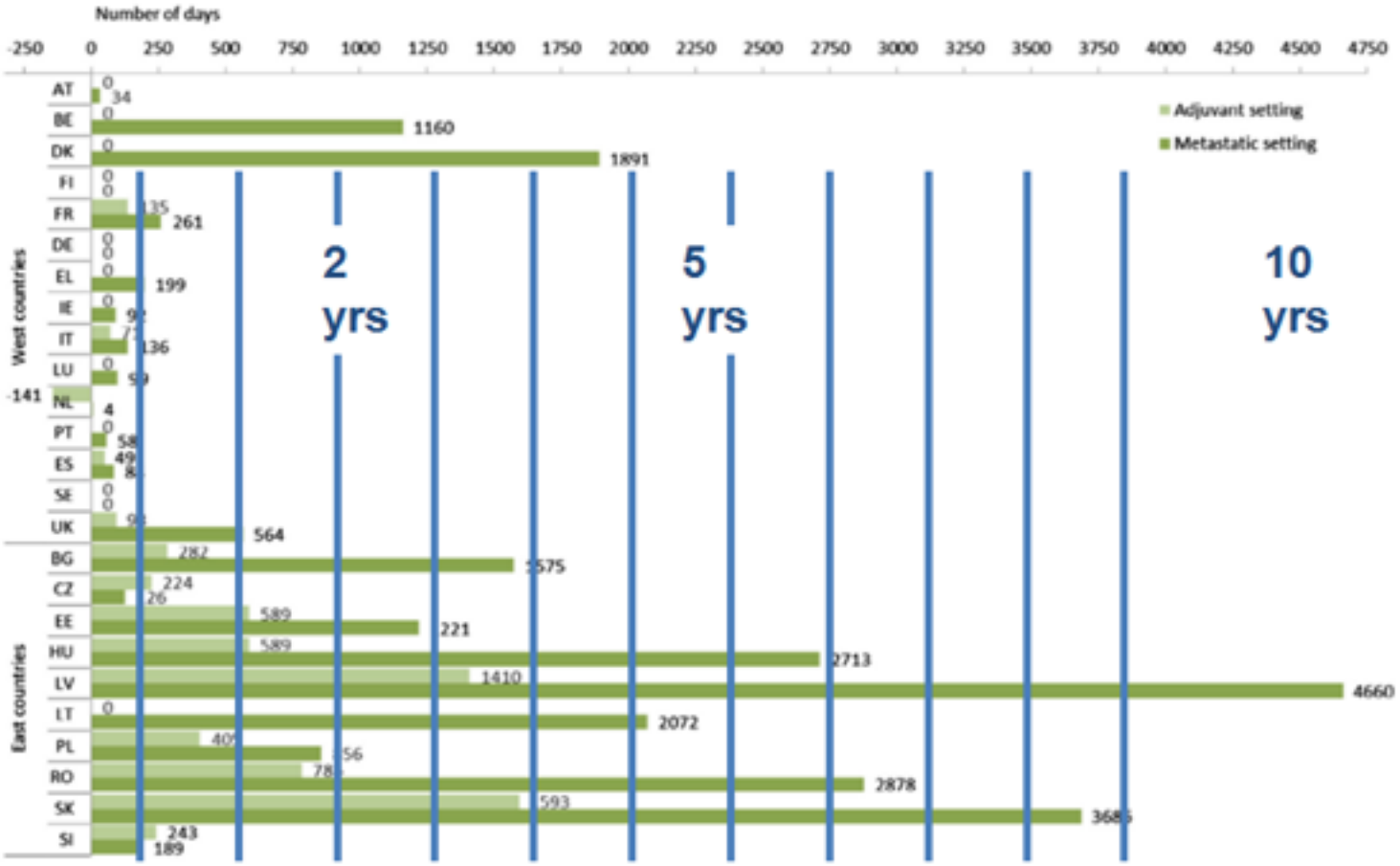

Fig. 1. Time periods for trastuzumab approval/reimbursement in the adjuvant and metastatic settings across European Union (EU) countries.

TAB. 3 - TEMPI PER LE SINGOLE PROCEDURE (EUROPEA, NAZIONALE, REGIONALE) DELL'ITER AUTORIZZATIVO COMPIUTO DAI FARMACI ONCOLOGICI (VAL. MEDI IN GIORNI)

Codice farmaco	Tempi in giorni		
	Procedura Ema	Da invio Aic in AIFA al PTOR	Totale Iter (Ema – PTOR) [1]
Panitumumab (III linea)	528	710	1.280
Denosumab	385	830	1.220
Vandetanib	442	590	1.140
Gefitinib	352	580	950
Ipilimumab (II linea)	435	710	1.130
Trastuzumabemtansine	386	400	800
Pertuzumab	-	570	1.030
Pasireotide	552	930	1.490
Everolimus	256	430	670
Afatinib	398	540	940
Paclitaxel - Albumina	227	-	-
Regorafenib	422	-	-
Regorafenib	295	-	-
Panitumumab (I - II linea)	515	950	1.530
Radio-223 dicloruro	282	-	-
Ipilimumab (I linea)	457	350	780
Media [2]	**400**	**630**	**1.070**

[1] Comprende anche il tempo intercorso tra procedura Ema ed invio in AIFA.

[2] Il valor medio è stato calcolato attraverso delle medie corrette, per motivi di robustezza rispetto ai valori estremi (*outliers*).

Fonte: elaborazione Censis su dati forniti dalle aziende e verificati sulla Gazzetta Ufficiale – Schede "Tracciabilità farmaci oncologici"

I principali risultati

7° Rapporto sulla condizione assistenziale dei malati oncologici

- Per il completamento del percorso autorizzativo trascorrono per i farmaci studiati in media 1.070 giorni, ovvero tre anni, così suddividi:
- fase europea 400 giorni;
- fase di invio all'Aifa 40 giorni;
- fase nazionale 530 giorni (290 per il lavori della Cts, 90 per il lavori della Cpr, 150 per la pubblicazione in Gazzetta);
- fase regionale 100 giorni per l'inserimento (ove presente) nei prontuari regionali.

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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

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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 90 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 include the patients in the HTA process to asses the true meaning of value

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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 Belgium, the Netherlands for exchange of information about pricing
- 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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Health Technology Assessment (HTA)

- Absolute need to harmonise HTA at European Level
- EUropean network for Health Technology Assessment (EUnetHTA)

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HTA cannot be solely a technical evaluation

Several other disciplines besides EBM must be involved:

- outcomes research,
- pharmacoeconomics,
- medical decision making,

all together form today's HTA

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Is HTA purely technical?

Figure 1. Health technology assessment (HTA) is an inter-disciplinary movement.

J.F.P. Bridges, Chr. Jones-Johns Hopkins Bloomberg School of Public Health-3rd Annual Meeting of HTAi Intl-2006

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Patients: an integral part of HTA evaluation

- Is it enough to give a seat at the decision making table to **"professionalized"** patients?
- Limited adoption of this hesitant approach by HTA agencies
- **The patient:** most important stakeholder in decision making for HTA
- Doctors: key in medical decision making- trusted by patients

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Patients: ready to be full partners of HTA process

E-patients=empowered, equipped, enabled, engaged patients of today request

- Focus on the **patient's problems**
- Take the **patient's perspective**
- Accomodate the **patient's preferences**

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The **best drug**

that does not reach the patient

in time & at reasonable price

is of no use to the patient

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Thank for your attention

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