Elisabetta Gardini MEP

Rome, 16th September 2016

CAN EU CANCER PATIENTS TRULY ACCESS INNOVATION?

PATIENTS LIVE A PARADOX:
NEW DRUGS EXIST, BUT THEY ARE NOT AVAILABLE IN TIME

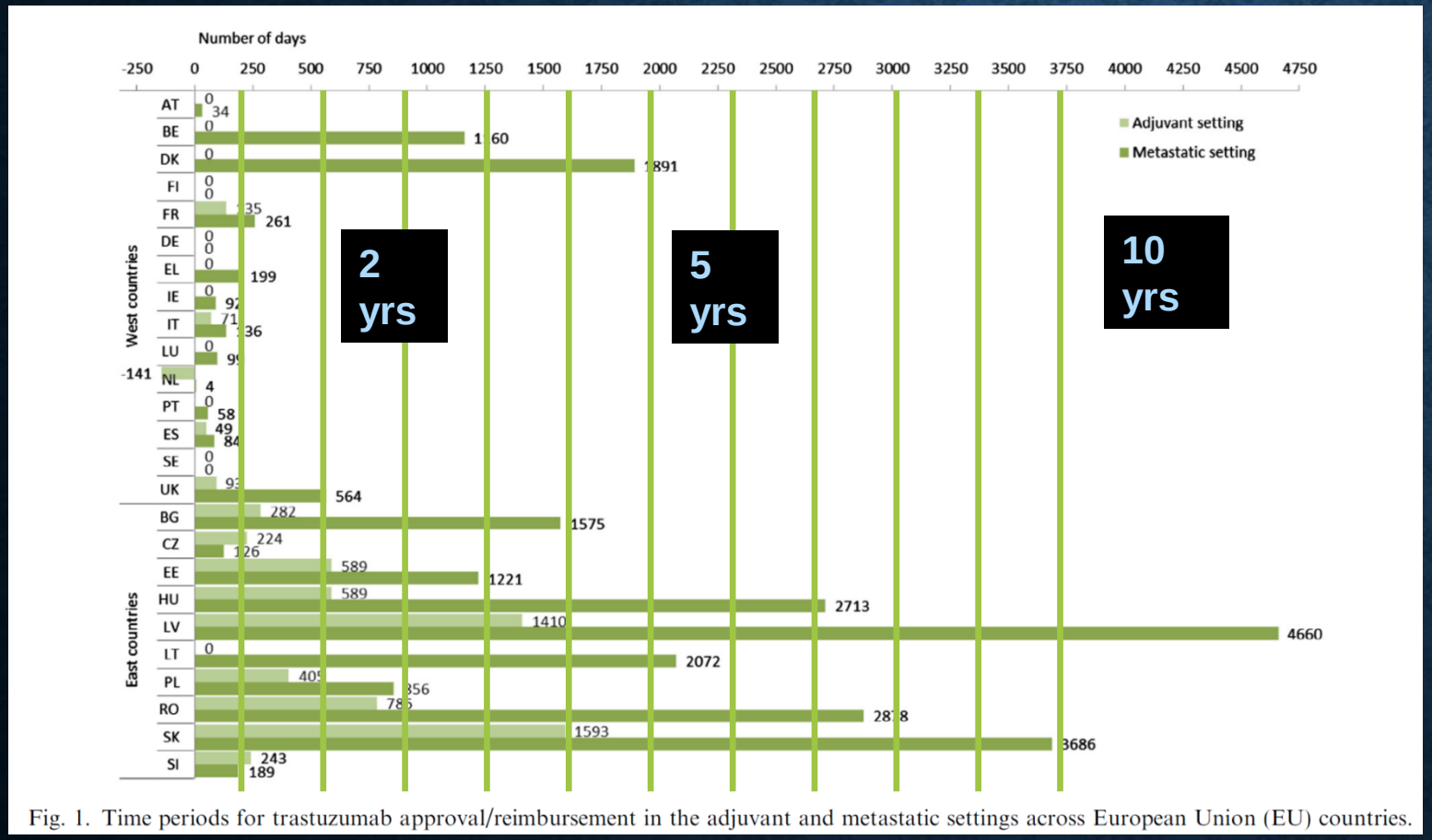
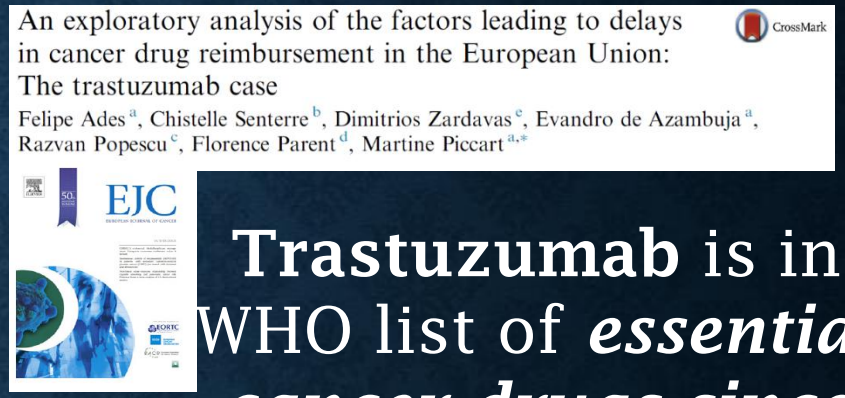


Fig. 1. Time periods for trastuzumab approval/reimbursement in the adjuvant and metastatic settings across European Union (EU) countries.



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

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EJC

Trastuzumab is in WHO list of ***essential cancer drugs since 2015!***

WE MUST WORK ON DELAYS AND INEFFICIENCIES!

THE PROBLEM: LACK OF HARMONISATION

- 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!

WHAT CAN BE DONE?

- 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

WHAT HAVE WE DONE SO FAR?

- Raising awareness
- Providing policy recommendations
- Push the European Commission to ACT!

Always in partnership with cancer patients (ECPC)

AWARENESS RAISING

27th January 2015: "Europe of Disparities" event at the European Parliament

- Hosted by MEP Gardini
- Keynotes from EU Commission (DG SANTE & ECFIN), Pharma (EFPIA) and to EU Researchers (Prof R. Sullivan)
- Outcome:
  - Inequalities in cancer care are not only related to access to essential drugs and treatments, ***but also to innovation!***
  - ***Sustainability is the key problem:*** innovation is not such if it is not accessible by anyone who needs/deserves it!

AWARENESS RAISING

4th February 2015 (World Cancer Day)
Declaration at the European Parliament

- Hosted by MEP Gardini and co-promoted by MEP Pedicini (EDDF), MEP De Backer (ALDE), MEP Grapini
- Launched at the European Parliament during press conference
- Key points of the declaration:
  - Member State must thoroughly implement CBHD
  - Member States must grant access to innovative, life-saving cancer medicines
  - Patients must be involve in healthcare decision-making process
- Outcome:
  - More than 160 MEPs endorsed the Declaration!

POLICY RECOMMENDATIONS

Debate at the European Parliament,
on ***"Sustainability of healthcare systems"***

9th September 2015

My suggestions:

- Sustainability is key to the ensure equitable access to cancer care
- ***Shortage of essential cancer drugs***
  - 86% of EU hospitals suffer from shortages of medicines, including cancer drugs
  - We need a EU system to monitor shortages of essential medicines
- ***Delays in approval of cancer medicines***
  - Cancer medicines are all centrally approved by the EMA
  - Pricing and reimbursement are however done at national level
  - This creates inefficiencies! The same medicines is evaluated 28 times, based on the same data!
  - It is time to harmonise part of the HTA processes at the EU level to cut times between lab and bed

POLICY RECOMMENDATIONS

ECPC policy strategy "Europe of Disparities in Cancer"
September 2015

- Complete, patient oriented, scientifically validated policy paper on the nature and cause of inequalities in cancer care = truly useful!
- It provided us key arguments to:
  - Improve access to essential cancer drugs
  - Improve access to innovative cancer drugs
  - Decrease delays in the approval, pricing and reimbursement of new medicines
  - Harmonise Health Technology Assessment

POLICY RECOMMENDATIONS THE WRITTEN DECLARATION 30/2015

- *Official document of the European Parliament*
- Proposal submitted by Gardini and 18 other MEPs
- Key assumptions:
  - The cancer patients paradox – new drugs exists but they are not available
  - Patients suffer from shortages of essential and innovative drugs
  - Non-coordinated HTA processes are creating inequalities in access and delays
- Key demands to the European Commission and the Council:
  - Undertake market research on causes of shortages, with particular attention to parallel trade
  - STRENGHEN COOPERATION AMONG MEMBER STATES ON HTA
  - Produce scenarios to create a EUROPEAN HEALTH TECHNOLOGY ASSESSMENT BODY
- **THE WRITTEN DECLARATION WAS SIGNED BY MORE THA 260 MEPS FROM ALL EU COUNTRIES!**

FROM RECOMMENDATIONS TO ACTION AMENDMENTS TO THE EMA REGULATION

- Regulation 726/2004 regulates the way EMA approves new medicines, including cancer drugs
- Entered revision in 2016
- We presented several amendments, calling for:
  - Harmonisation of the HTA process at EU level
  - Relative efficacy assessment to be done once for all EU countries
- Result:
  - Amendments approved with very large majority in ENVI Committee and included in draft regulation
  - New 726/2004 APPROVED by the European Parliament (plenary) in March 2016
- Next steps
  - Waiting for an official position of the Council of the EU

THE IMPACT OF OUR WORK

- **Commissioner Andriukaitis** welcomed the amendment proposed and publicly supported the concept of harmonising HTA at the EU level (June 2016)
  "*My services have therefore started a **reflection process** of the current situation on EU cooperation on HTA and the **identification of possible policy options**"*
- **Commissioner Andriukaitis** supported our position vs parallel trade and called for a revision of the single market rules to protect patients
  "*EU member states have the right to regulate parallel drugs trade. Slovakia took this kind of measure, Poland too"*
- **EMA Director Prof Rasi** also praised the spirit of the amendments, and called for **further harmonisation of the HTA evaluations across Europe**, and for an **increased level of collaboration** among Member States in relation to **new approaches to evaluating medicines' innovation**, like the collection of real-world data.
  "I think this is evidence that working together generates added value and added knowledge for us [EMA] and them [national HTA bodies], and really puts that trajectory in the right direction … I think we just have to strive for that"

WHAT IS NEXT?

- Innovation is meaningless if it is not sustainable
  - New cancer drugs cannot increase the existing inequalities in access, but help to fight those inequalities!
  - Innovation is meaningful ONLY if:
    - Made accessible to patients
    - Our healthcare systems can afford it
  - The EU has a role to play in ensuring that pricing and reimbursement strategies ensure that innovation arrives fast and in an equitable way to the cancer patient
  - October 2016: the EP will start discussing on a own initiative report on access to medicines = Key battleground for our position on access to innovation
- Public consultation following meeting with Andriukaitis

11/05/2016