Ensuring access to innovative cancer drugs: the role of diagnostics

Alina Comanescu, President of Health for the Community & ECPC Member
CDDF 9th Alpine Conference
# Health for the Community

## How?

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

- Position papers and policy studies
- Awareness-raising events
- EU institution advocacy

- Working Groups
- ECPC Masterclass
- General Assembly
- Education & Courses
- Advocacy Training

- CANCON
  - Members of the EC Expert Group on Cancer Control
  - Members of the European Initiative on Breast Cancer
  - Health Policy Forum
  - EMA's Patients' and Consumers' Working Party
  - CDDF
  - EAPM
  - ECC
  - EORTC
  - ESMO/ECCO
  - OECI
  - UICC

- EurocanPlatform
- eSMART
- RARECAREnet
- InSup-C
- BenchCan
- Transcan 2
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)
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
The education problem

Patients and HCPs literacy
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
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
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](http://www.iop.ecpc.org)
## List of the Expert Group members

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<tr>
<th>Name</th>
<th>Institution</th>
<th>Country</th>
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<tr>
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<td>Prof Giuseppe Masucci</td>
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<tr>
<td>Prof Heinz Zwierzina</td>
<td>Head of the Early Clinical Trial Unit, Innsbruck Medical University</td>
<td>Austria</td>
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Understanding Cancer Immunotherapy and Immuno-Oncology:
A Guide for Patients

Module 2: Immuno-Oncology Treatments
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.
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.

- T-cells infiltrate the tumour site
- Upon imaging there is the appearance of tumour flare or new lesions

**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.**
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
PATIENT AWARENESS ON BIOMARKERS ACROSS EUROPE

Do you know that biomarkers can help doctors find the best treatment for you?

60% of the respondents have never been offered a biomarker test by their oncologist.

50% of the respondents to ECP survey are aware of the existence of biomarkers.

70% of the respondents to ECP survey have never been proposed a biomarker testing by their oncologist.

Have you been offered a biomarker test by your oncologist/physician?

How long did it take for you to get your biomarker test result?

70% said that the importance was not adequately explained.

Did your doctor explain to you the importance of biomarker tests?

70% of the respondents to ECP survey were not reimbursed for any type of cancer.

Where did you find information about biomarkers to educate yourself?

Are biomarkers reimbursed in your country?

Success story

A young woman who never smoked and who was suffering from lung cancer was not offered molecular testing by one of the most famous hospitals in Rome. According to ESMO, USLCC and AJOM guidelines, she should have been entitled to this test, as her cancer was an adenocarcinoma. The patient subsequently requested a second opinion from a hospital in Perugia, a small city in Italy. The physicist in this hospital tested her at once and she was found to be ALK+. This result allowed her to be considered for treatment with a targeted therapy that was only available via clinical trial. Fortunately, the hospital was taking part in a trial and she was enrolled and treated by the hospital in Perugia.

The patient is still alive after three years and she has almost a normal "quality of life" with very few side effects.

This initiative was carried out with the support of

AMGEN | MERCK | MSD
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
- Social media campaign and dissemination of the ECPC leaflet to our Members
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…)
The cost problem:

Can cancer patients access innovation?
Patients’ paradox
Can we truly access innovative drugs?

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, e

Fig. 1. Time periods for trastuzumab approval/reimbursement in the adjuvant and metastatic settings across European Union (EU) countries.
Inequalities (survival) in cancer care: European reality

The example of colorectal cancer

Inequalities in cancer care: an economic problem

Example: avg. cancer expenditures per citizen in the EU

€/citizen

Europe 102
Bulgaria 16
Romania 20
Poland 37
Portugal 53
UK 85
Spain 94
France 110
Italy 114
Germany 182

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!
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!
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)*
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
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
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 assess the true meaning of value
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
<table>
<thead>
<tr>
<th>Key characteristics</th>
<th>Option 1</th>
<th>Option 2</th>
<th>Option 3</th>
<th>Option 4</th>
<th>Option 5</th>
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<tr>
<td>Regulatory</td>
<td>Non-legislative</td>
<td>Non-legislative</td>
<td>Legislative</td>
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<td>Participation of HTA bodies and industry</td>
<td>Voluntary</td>
<td>Voluntary</td>
<td>Compulsory (tools) Voluntary / compulsory (HTA)</td>
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<td>Uptake joint output</td>
<td>Voluntary</td>
<td>Voluntary</td>
<td>Compulsory for tools</td>
<td>Compulsory for tools and REA</td>
<td>Compulsory</td>
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<tr>
<td>Financing</td>
<td>Largely depending on EU budget</td>
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<td>Mixed funding model (EU budget + MS + industry contribution)</td>
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<td>Main joint output</td>
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<td>a. Common Tools/templates</td>
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<td>b. Joint REA</td>
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<td>c. Joint Full HTA</td>
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<td>d. Early Dialogue</td>
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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
    • 1\textsuperscript{st}: recommendation from the doctor, paired by personal dossier on individual patient (including paediatric cancer patients!!)
    • 2\textsuperscript{nd}: 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
Thank for your attention

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European Cancer Patient Coalition

ECPCtv

Nothing about us without us!