Topic 5: Challenges of the combination of Targeted Therapies

Patients’ Access to Precision Oncology

Francesco de Lorenzo, ECPC President
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President of the European Cancer Patient Coalition (ECPC), a registered non-profit umbrella patient organization, which receives funding from a variety of sources including the European Commission based on project grant agreements.
Who are we?

▪ ECPC is the largest European cancer patients' umbrella organisation.
▪ Representing more than 400 organisations in 46 EU and non-EU countries.
▪ Our Vision

ECPC works for a Europe of equality, where all European cancer patients have timely and affordable access to the best treatment and care available, throughout their life. ECPC believes that cancer patients are the most important partners in the fight against cancer and against all the cancer-related issues affecting our society. Policy makers, researchers, doctors and industry should recognise cancer patients as co-creators of their own health.
ECPC’s Multi-Annual Strategy 2016 - 2019

**Governance**
Build a sustainable governance model

**Policy**
Influence the EU legal framework and the European and national political agenda

**Capacity-building**
Empower cancer patients organisations, and enhance their abilities to shape national policy

**Research**
Increase the role of patients in cancer research
Personalised medicine: the future of Cancer treatment

- Personalised medicines is considered the future of cancer care giving patients the best treatment according to their personal medical history, physiological status, and molecular characteristic of their tumours.

- Results from an international study show that revolutionary genetic testing of tumours can boost survival rates and avoid unnecessary treatments, shrinking tumours at 6 times the rate of conventional medicines – Cancer Research UK 2016.

- News Study illustrates that matching treatment to genetic changes in the tumour improves survival across multiple cancer types – ASCO 2018.

- Personalised medicine is the future of cancer treatment and should be standard practice.
Barriers to innovative medicines
Personalised Medicine challenges and barriers

• Personalised medicine has the potential to allow patients to receive drugs specific to their individual disease and increase the overall efficiency of the healthcare system.

• Personalised medicine is predominantly focused on patient stratification according to individual biological information and does not take into consideration patients’ preferences in decision making.

• Personalized medicine is a relatively young field and, accordingly, a future focus shifting from treating diseases to managing patients.

• We need to adapt the way we design clinical trials in order to target specific genetic alterations. Truly personalized treatment approaches can be seen to include a much more comprehensive assessment of genetic and even lifestyle factors.

• There is a delay between the advance of research and the parallel innovation of the healthcare system. Healthcare professionals need to pool the knowledge on precision medicine.

• The cost and affordability of anticancer treatments with recent market approval are major factors contributing to inequity and timely access to anticancer medications. This is especially true with regards to new medications.
The problem: patients live a paradox: can we truly access innovation?

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

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Felipe Ades, Chistelle Senterre, Dimitrios Zardavas, Evandro de Azambuja, Razvan Popenea, Florence Parent, Martine Piccart

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Fig. 1. Time periods for trastuzumab approval/reimbursement in the adjuvant and metastatic settings across European Union (EU) countries.
ESMO 2016: Thousands of Melanoma Patients in Europe Have no Access to New Life Saving Drugs

• Before 2011 there were no effective treatment options for metastatic melanoma patients, but that has changed tremendously in the last 5 years.

• Now, we have medicines which can prolong overall survival of these patients to more than 18 months and, in some patients, durable responses lasting up to 10 years.

• However, access to these medicines is limited and patients and physicians are facing increasing difficulties to obtain them e.g. Eastern and South Eastern European countries.

• Over 5000 patients with metastatic melanoma in Europe are denied access to new, life saving drugs every year, according to a survey presented at the ESMO 2016 Congress in Copenhagen.

• The survey showed that in Western Europe 70% of patients were treated with innovative medicines, while in Eastern Europe less than 10% of patients had access to the latest treatment recommended by current European Guidelines.
Value of medicine

- True, **value-based healthcare**, in which systems guide their decision are not only based on the ratio of outcomes to cost, but also on the **clinical efficacy** and **value of pharmaceutical treatments** in terms of **clinical benefit**, **quality of life**, **social benefits** and **economics**.

1. **Access to innovative drugs**: Access to medicines is a substantial component of universal health coverage, however, current dynamics between the innovative pharmaceuticals and approval mechanisms in emerging markets may be counterproductive to sustainably increasing access to current and/or future patented medicines.

2. **Delivery of effective and timely health care**: The health care delivery system often does not interact **effectively** in the 28 EU Member States delaying **timely diagnosis and treatment**.

3. **Difficulty in access to biomarkers**: Development of biomarker-based diagnostics can facilitate faster diagnosis and treatment, however, diagnostics tests need to be integrated in the clinical setting and be affordable and available to all patients.
▪ ECPC succeeded in working with the European Commission to develop a proposal for EU HTA cooperation.

▪ **HTA Harmonisation:** the European Commission (EC) set out plans for a **more harmonised approach** to Health Technology Assessment (HTA) across Member States (MS) at the end of January 2018 **through 1 joint assessment**. Currently, there are 56 public bodies in 27 EU countries and Norway that do HTA at the national level and only 15 countries have a single HTA agency.

▪ This proposal would strengthen regulatory cooperation, take advantage of **early scientific advice**, **accelerate clinical assessments**, and **improve access to medicines**.

▪ Once it passes through the European Parliament, it is urgent that the Council approves this proposal.
ECPC Advocacy Milestones

- The European Cancer Patient Coalition has been advocating for a harmonised Health Technology Assessment in the EU since 2014.

2014
- The European Bill of Cancer Patients Rights
- European Parliament Declaration on World Cancer Day

2015
- Changes to European Regulation 726/2004
- Europe of Disparities

2016
- Response to European Commission Consultation on HTA Cooperation

2017
- European Parliament report on Options for Improving Access to Medicines

2018
- The European Commission’s proposal on HTA Cooperation
- Meeting with EU Commissioner Vytenis Andriukaitis
- European People’s Party Manifesto against cancer
- ECPC’ Position Paper
Budget of Silos

Silos commonly understood:

• It is the division of resources between medicines, medical devices, hospital assistance, which through budget and separated responsibilities prevent compensation between expenditure items concerning health and social protection

• Example – innovative drug

- Increases pharmaceutical expenditure + Pharmaceutical expenditure Costs
- Reduces hospitalisation – Hospital costs
- Reduces use of specialists – professional services costs
- Reduces illness – Social security costs
- Increases working capability + Increased production capability
Health Technology Assessment Domains

Clinical Domains (REA)

1. Health problem and use of current technology
2. Description and technical characteristics
3. Safety
4. Clinical effectiveness

Non-clinical Domains

5. Cost and economic evaluation
6. Ethical analysis
7. Organisational aspects
8. Patient and social aspects
9. Legal aspects
HTA Regulation Approval Timeline

- **Commission proposal**
- **Entry into force**
- **Date of application**
- **Transition period**
- **All MS**

- Member States **may delay their participation** in the system of JCA and JSC until **3 years after the date of application**
- **Prioritization** of health technologies subject to JCA, JSC
Barriers to biomarkers
Biomarker testing challenges in Europe

• Biomarkers are essential part of a targeted approach to the prevention, diagnosis and treatment of cancer, based on an individual's specific profile.

• **Accessibility** of biomarker testing varies from country to country, but also within cities and regions.

• **Administrative barriers** lead to delays and higher waiting periods for biomarker test results which vary from a few days to an entire month in some countries. There is no established organization between hospitals to perform test and share the results.

• **Reimbursement** of biomarker testing also varies by country. For example, the RAS Biomarker Testing is reimbursed at varying rates in 21 of the 28 EU Member States.
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Reimbursement of RAS biomarker molecular testing for colorectal cancer
What is the state of cancer biomarkers in Europe?

Only 23% of European Doctors felt that their patients were always fully informed about biomarker testing

ECPC -EAPM: Biomarkers Survey 2016
Biomarkers at the EP

The event brought together patients, policy-makers, researchers and the industry to discuss the importance of biomarkers for people with cancer, and the necessary actions needed to make precision medicine in cancer a reality across Europe.

ECPC called for more **progress to be made towards a harmonised and more efficient regulatory framework** which will increase access to and potentially reduce the cost of biomarker testing.

Participants also highlighted the need for increased access and decreased waiting times for high-quality biomarker testing to make personalised healthcare more of a reality.
The European Cancer Patient Coalition is calling for:

- Increased access and decreased waiting times for high quality biomarker testing to make personalised healthcare more of a reality across Europe.

- Awareness campaigns that increase biomarker literacy, by increasing patients' understanding of where they need to go to access biomarker testing.

- Progress towards a harmonised and more efficient regulatory framework, which could increase access to and potentially reduce the cost of biomarker testing.
Our Activities

- December 2017, event at the European parliament championed by MEP Mizzi.

- More progress to be made towards a harmonised and more efficient regulatory framework which will increase access to and potentially reduce the cost of biomarker testing.

- Jan 2018 launch of the ECPC Educational Video on Biomarkers.

- The European Liquid Biopsy Academy (ELBA): an innovative training network that will educate early stage researchers with the skills to circumvent obstacles currently hampering the effective development of blood-based diagnostic tests, create a sustainable network to foster long-term multidisciplinary relationships to accelerate clinical translations of blood-based diagnostics tests and publish a roadmap to liquid biopsy test development.
This initiative has partners from **24 countries** across Europe, and will **build upon CanCon and implement innovative approaches to cancer control**.

ECPC is involved in the work packages dedicated to **genomics, registries, and challenges**.

**ECPC will be working to:**

- Enhance population-based cancer information systems to better support evidence-based comprehensive cancer care.
- Develop practical guidance on successfully integrating genomics in the health system.
‘Biomarkers and Access to Innovative Oncology Drugs in Europe’

- The European Cancer patient Coalition (ECPC) in partnership with the Cancer Drug Development Forum (CDDF) will be hosting an even at the European parliament be linked to Austrian Presidency of the Council of the European Union.

- **Date:** 24 & 25 September in Brussels
As part of the Patient Track at the European Alliance for Personalised Medicine (EAPM) congress, ECPC will host a session on 28 November 2018 in Milan, on ‘Biomarker Health Literacy’.

Topics:

- Biomarkers Overview
- Biomarkers – more than just companion diagnostics
- Ensuring a sustainable health system
- ECPC Personalised Medicine Awareness Month
Barriers to Healthcare systems
ECPC is a partner in several European Commission Joint Actions. The Joint Action on Cancer Control (CanCon) was a common effort between 17 countries, 126 partner organisations, and cancer experts.

CanCon's Policy Paper "European Guide on Quality Improvement in Comprehensive Cancer Control“ has recommendations to improve access by updating obsolete procedures and eliminating waste to find funds for innovation.

Patients should be at the centre of this process, and should be treated in centres of excellence. The European Reference Networks are a good model for harmonisation of treatment that demonstrates implementation of the Cross-border Healthcare Directive.

In order to ensure the sustainability of the healthcare system, better access to biomarker molecular testing is needed.

Biomarker molecular testing is critical to identify the people who may benefit from different types of cancer treatment and avoid treatment-related toxicity.
The Joint Action on Cancer Control – CANCON was a common effort between representatives from 17 EU Member States, co-funded by the European Commission to create guidelines for harmonization of national cancer plans.

European Cancer Patient Coalition was a vital partner in this Joint Action

- Unacceptable situation in Europe
- Identification of key needs directly from patients’ organisations
- Support in setting priorities / making the document actual and politically actionable

Policy paper on ‘Enhancing the Value of Cancer Care Through a More Appropriate Use of Healthcare Interventions’
- Identified what the role of patients organisations can be
- Setting up a roadmap to better involvement of patients
- Helped to set the priorities and examples

Policy paper on ‘Recommendations for quality improvement in cancer survivorship and rehabilitation in EU Member States’
- Help defining cancer patients needs (different types of rehabilitation, return to work, socio-economic issues);
- Strong support to SCP
- Connection between the recommendations and medical societies
CanCon Joint Action

“...reducing social inequalities in cancer is a top priority within European and national strategies on cancer prevention and control, especially through the National Cancer Control Plans.”

- **Recommendation 1:** Embed equity within the cancer prevention and control policies in all European Union Member States.

- **Recommendation 2:** Align cancer prevention and control policies with a Health in all Policies approach.

- **Recommendation 3:** Adopt a Health Equity Impact Assessment framework.
CanCon Joint Action

‘.. Improve access by updating obsolete procedures and eliminating waste to find funds for innovation. Patients should be the centre of this process.’

• **Recommendation 1:** Policies aimed at reducing low-value oncologic care should be appropriately framed, emphasizing the goal of enhancing quality of care, rather than merely reducing healthcare costs.

• **Recommendation 2:** Withdrawing (totally or partially) resources from low-value or inappropriate care should be linked to sustaining patient access to good quality care, addressing both the issue of underuse of existing valuable interventions and access to innovations whose actual clinical value has been properly assessed.
Thank you!

“Nothing about us without us!” ECPC