

Cancer Biomarkers in the Era of Personalised Medicines



TUESDAY 5 DECEMBER 2017
15:00 – 17:00

EUROPEAN PARLIAMENT | ROOM A1E-1

Hosted by MEP Marlene Mizzi (S&D, Malta)

EVENT REPORT

INTRODUCTION

On 5 December 2017, the European Cancer Patient Coalition (ECPC), in collaboration with the Member of the European Parliament Marlene Mizzi (S&D, Malta) organised an event on the topic of *Cancer Biomarkers in the Era of Personalised Medicines*. 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.

Cancer biomarkers are molecules that are usually produced by cancer cells and that can be detected in bodily fluids or tissues. They can identify people who have cancer or who are at risk of getting cancer.

Biomarker testing helps to identify the “Achilles' heel” of different types of cancer, ensuring that the right person receives the right treatment at the right time.

The event served also as a launch platform for the ECPC educational video on biomarkers, which will be made available on the ECPC website in January 2018. The ECPC, through its President and co-founder, Prof. Francesco De Lorenzo, 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 conference was moderated by ECPC Head of EU Affairs, Alex Filicevas.

INTRODUCTORY REMARKS



MEP Marlene Mizzi (S&D, Malta) opened the event by welcoming the participants and noting that cancer has been high on the political agenda for a good reason. She recalled that more and more European citizens are likely to experience first-hand the illness themselves or through a family member or a friend. Ms. Mizzi stressed that cancer biomarkers could enhance the chance of people with cancer to receive more personalised treatment, appropriate for their specific condition. She further acknowledged the challenges faced by precision medicines, such as awareness and usage. Patient empowerment being a goal for both politicians and

patient organisations, Ms. Mizzi emphasised the need to increase patients' and policy-makers' understanding of cancer genetic testing and endorse awareness campaigns that increase health literacy by improving knowledge. She was pleased to start her collaboration with the ECPC and ended by endorsing their efforts in the field of cancer patients.

BIOMARKERS IN DRUG DEVELOPMENT AND RESEARCH



Prof. Heinz Zwierzina from the Innsbruck Medical University and the Cancer Drug Development Forum presented the importance of biomarkers in drug development and research. He noted that cancer biomarkers are needed, as they can support fast and comprehensive drug development and the design of a tailored therapy for patients. Prof. Zwierzina specifically noted the crucial role biomarkers are playing in personalised therapy and presented the ONCO-T-Profiling project, a collaborative effort between the University of Innsbruck and Caris Life Sciences. He called for the development and usage of complex biomarkers.

With shortcomings of single biomarkers and the complexity of cancer biology, he noted that complex biomarkers will be increasingly relied on. He concluded by stating the need for biomarkers that define subgroups of patients that may or may not respond to therapy.

THE IMPORTANCE OF BIOMARKERS FOR PEOPLE WITH CANCER

Dr. Nicola Normanno from the Fondazione Pascale spoke about the importance of biomarkers for people with cancer. He stressed that molecular alterations in cancer cells offer potential for therapeutic intervention with “target-based agents”. Furthermore, in order to promote precision oncology, he noted that we must:



1. Guarantee access to biomarkers to cancer patients in all European countries.
2. Promote technological evolution towards innovative testing methods that allow the identification of several markers for analysis.
3. Identify reference centres with adequate experience and technological.
4. Facilitate national and international collaborations to assess the predictive role of rare mutations.
5. Guarantee access to new drugs available in clinical practice or through clinical trials.
6. Ensure that the quality of the tests received by cancer patients is high.

THE IMPORTANCE OF PRECISION MEDICINES IN CANCER



Building on what was presented before, **Prof. Mark Lawler** from the Queen's University Belfast and the European Alliance for Personalised Medicines, presented the importance of precision medicine in cancer. Prof. Lawler noted that precision medicine and the use of biomarkers are the key components of the 21st Century Medicine. Furthermore, precision medicine offers new preventative/therapeutic opportunities while also sparing patients the debilitating effects of treatment toxicity. He stated that when used appropriately, biomarker driven precision medicine can be cost effective.

His final take home message was on sharing data as a way to maximise the benefit of precision medicine. Prof. Lawler called for championing a data sharing culture, establishing a cancer knowledge network and moving to an open source collaborative culture.

PERSONAL TESTIMONY FROM CANCER PATIENT

The event was marked by a personal testimony from **Anne Micallef**, the President of the Breast Cancer Support Association – Europa Donna, Malta. Following an overview of survival rates for ovarian cancer, Anne shared with the audience her touching personal experience with cancer and cancer biomarkers. Having beaten cancer, largely due to a biomarker test, she is currently doing annual mammogram and ultrasound and six-monthly check-ups with cancer biomarkers.



THE INDUSTRY PERSPECTIVE



The industry perspective on the important topic of cancer biomarkers was presented by **Dr. Darko Miljkovic** from the European Federation of Pharmaceutical Industries and Associations and the European Biopharmaceutical Enterprises. Dr. Miljkovic spoke about biomarkers and companion diagnostic¹, which has transformed the way cancer is treated. He stressed the need of companion diagnostic to be integrated in international and local clinical guidelines. Dr. Miljkovic finally called for the establishment of locally suitable testing pathway so that patients can access the testing, supported by education, training and

funding mechanism.

¹ A device which is essential for the safe and effective use of a corresponding medicinal product to (a) identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or (b) identify, before and/or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product (Regulation (EU) 2017/746)

GERMAN PERMANENT REPRESENTATION TO THE EU



Ortwin Schulte from the German Permanent Representation to the EU made a short intervention about the special role of health policy in the EU. He also stressed the aspects of the limited EU legislation competences on health and highlighted the topic in the non-legislative political EU health cooperation (e.g. Presidency programs). He noted the upcoming proposal on health technology assessment, which will be announced by the European Commission in late January 2018. He also informed participants that a politically sensible debate amongst the Member States whether there is a need for more Regulation on price transparency of pharmaceuticals is currently on-going.

Mr Schulte concluded by emphasising the importance of raising awareness at EU level on health cooperation.

CALL FOR ACTION

The European Cancer Patient Coalition President, **Prof. Francesco De Lorenzo**, presented the ECPC commitments to improve cancer patients' treatment outcomes, including the ECPC-European Alliance for Personalised Medicines survey. He noted that cancer biomarkers are still largely unknown to patients. Prof. De Lorenzo, also presented for the first time the ECPC video animation on cancer biomarkers, which was developed based on a Multinational Survey Comparison of Physicians and Patients by the Oncologist Journal (2016) – *Awareness, Understanding, and Adoption of Precision Medicine to Deliver Personalised Treatment for Patients with Cancer*. The short video, well received by all participants, will be available on the ECPC website in January.



The European Cancer Patient Coalition made a three-point call for action:

1. ***Health authorities, physicians and patient groups need to improve awareness regarding genetic testing.***
2. ***Diagnostics tests need to be integrated in the clinical setting and be affordable and available to all patients.***
3. ***The regulatory and reimbursement processes must be adapted to the specificities of new technologies. A better integration of diagnostic regulations into therapeutic regulatory frameworks could improve the reimbursement and access of biomarker tests.***

DISCUSSION



The presentations were followed by a lively discussion session, moderated by the ECPC Head of EU Affairs, Alex Filicevas. Participants elaborated on the need to improve the possibility for patients to participate in clinical trials.

Speakers discussed the importance to have both companion diagnostic and biomarkers with an adequate regulatory framework allowing reimbursement and access to these tests.

Another crucial subject touched upon was data. Specifically, for retrospective analysis, participants talked about harmonized standards, in the absence of which data analysis may vary from a laboratory to laboratory. It was agreed that a common standardized platform for analysing data would be more than welcome.

Prof. De Lorenzo concluded the session by stressing once again the importance of collaborating with other stakeholders, such as the European Society for Medical Oncology, with whom the ECPC has already a long-standing collaborative relationship.



LIST OF SPEAKERS (IN ORDER OF THE AGENDA)

- Marlene Mizzi, Member of the European Parliament
- Heinz Zwierzina, Cancer Drug Development Forum
- Nicola Normanno, Fondazione Pascale, Napoli
- Mark Lawler, Queen's University Belfast and the European Alliance for Personalised Medicines
- Anne Micallef, Europa Donna, Malta
- Darko Miljkovic, EFPIA/EBE
- Ortwin Schulte, German Permanent Representation to the EU
- Francesco De Lorenzo, European Cancer Patient Coalition
- Alex Filicevas, European Cancer Patient Coalition (moderator)

LIST OF PARTICIPANTS (IN ALPHABETICAL ORDER)

- Adriana Muscolo, FTI Consulting
- Andy Dyson, MSD Europe
- Anissa Brennet, Cancer Drug Development Forum
- Anja Strootker, Invite PA
- Anna Szczepanska, European Federation of Pharmaceutical Industries and Associations (EFPIA)
- Audrey Wolf, European Biopharmaceutical Enterprises (EBE)
- Belinda Whitehead, Porter Novelli
- Betty Holmes, Donegal Action for Cancer Care
- Carmel Micallef, Europa Donna, Malta
- Ciara Romero, Hanover Communications
- Desislava Dimitrova, Assistant to MEP Marlene Mizzi
- Dimitri Pouradier Duteil, Bristol-Myers Squibb
- Elena Alberti, European Cancer Patient Coalition
- Elena Thevissen, Assistant to MEP Marlene Mizzi
- Els Van Valckenborgh, Cancer Centre ISP, the Netherlands
- Hugh Pullen, Merck
- Jacqueline Bowman, Third-I bvba
- Jelena Malinina, RPP Group
- Jenny Shum, AstraZeneca
- Joao Marinho, Hitachi
- Kit Greenop, RPP Group
- Kathi Apostolidis, European Cancer Patient Coalition
- Leander Hahn, ODP
- Malvika Vyas, European Society for Medical Oncology
- Marie Kelly, Donegal Action for Cancer Care
- Marjorie Recorbet, Cancer Drug Development Forum
- Matti Jarvinen, Association of Cancer Patients, Finland
- Mihaela Militaru, Merck

- Minxian Conge, Abbvie
- Patrick Jongeleen, European CanCer Organisation
- Paul McCleverty, Janssen
- Stephanie Kohl, European Association of Hospital Pharmacies
- Stephen Mifsud, Maltese Permanent Representation to the EU
- Yordan Aleksandrov, RPP Group