BUILDING A EUROPEAN ECOSYSTEM TO BEAT CANCER

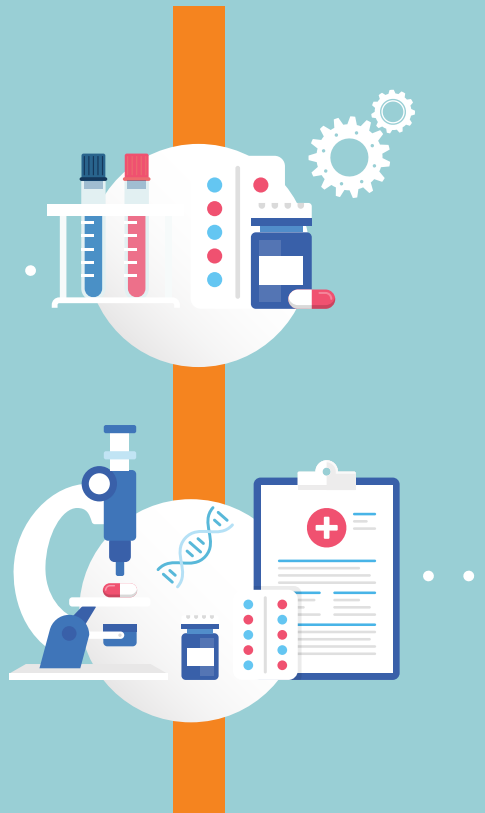
efpia
European Federation of Pharmaceutical Industries and Associations

Cancer is not one disease, but a constellation of diseases of immense complexity that cannot be solved by only one approach. Over the last decades, we witnessed some incredible advances in cancer care. A combination of preventative programmes, timely diagnosis, and advances in treatment are helping to extend people's lives. And research continues at pace: with over 1,300 cancer medicines in development and over 1,200 oncology clinical trials started in 2020, #WeWontRest in our mission to reduce preventable cancers and improve care for people living with the 66% of cancers which are not preventable.

Europe's Beating Cancer Plan **and the** ***Mission on Cancer*** **could herald a new era for cancer care with the potential to have a major positive impact on Europe's citizens. Their success will require broad political support, an inclusive and collaborative mindset, continued investment, and new initiatives, including public-private partnerships, to boost innovation. We – the EFPIA Oncology Platform – call on EU and national policymakers to build a research and access environment to support medical innovation in Europe and help deliver new treatments for the benefit of people living with cancer, their families and society as a whole. Our capacity to keep on developing new treatments depends on:**

A stable and predictable intellectual property (IP) and incentives framework to encourage, sustain and protect investment in the next generation of cancer treatments.

The IP framework[1] is fundamental to support research in new medicines, by providing a limited period of exclusivity thereby encouraging companies to invest into risky and lengthy research and development processes. Changing this framework risks undermining the innovation process that patients, healthcare systems and society rely on.



A stable, fast, effective, and globally competitive regulatory framework.

To keep pace with developments in science and technology and deliver safe and high-quality treatments to patients as fast as possible, Europe's regulatory framework needs to[2]: encourage the use of new types of clinical trial supported by science, modelling, data and AI; accelerate the use and acceptance of real-world evidence in regulatory decision making; allow ongoing dialogue and discussion about new medicines throughout development; align on novel and clinically relevant endpoints and metrics for new treatment options; and simplify how drug-device combinations are regulated.

A simpler marketing approval process for cancer cell and gene therapies containing or consisting of GMOs.

The absence of a harmonised approach across the EU has significantly limited companies' ability to run trials in the EU and to build strong clinical data packages in support of gene and cell therapies. We call for a simplified approach for GMO assessment and greater harmonisation in clinical trial application procedures.

A modern and improved EU marketing authorisation process.

Only 58%[3] of therapies licensed in the USA reach Europe in a comparable timeline. The revision of the Pharmaceutical Regulation provides a unique opportunity to optimise regulatory timelines to improve time to patient access to cancer therapies, both the scientific and non-scientific parts of the process[4].

Robust methods for identifying, collecting, analysing, and reporting cancer patient experience data.

Such methods can support regulatory and access decisions across EU Member States. To this day, it is still challenging for us to determine how the European Medicines Agency (EMA) uses cancer patient experience data in regulatory decision-making. This is particularly problematic for therapies potentially addressing high unmet medical needs. To move towards a harmonised and systematic approach to the application of Patient Experience Data (PED) in regulatory decision-making, a shared learning model should be developed, and the EMA should clarify in its assessment documents how patient experience data submitted in sponsor applications were used in each application.

Innovative value assessment processes to accelerate pricing and reimbursement decisions.[5]

Proper implementation of the EU Health Technology Assessment (HTA) regulation will avoid duplications and further delays to timelines at national level. A 'fit-for-purpose' HTA methodology is essential to lead to high-quality outputs that can be used by diverse national HTA bodies. HTA processes should be adapted to the specificities of highly innovative therapies, such as combination therapies and ATMPs (advanced therapeutic medicinal products).[6] Decisions on pricing of innovative medicines should be based on the value they deliver for patients, as well as the benefits for national health systems and societies.

The right environment for precision oncology to deliver its value for patients.

Through precision medicine, we can envision a future where we can intervene in every step of the cancer continuum, delivering value for patients, health systems and society. To realise this potential we need harmonised policies, living guidelines for screening and alignment across approval and reimbursement regulations that adapt quickly to the evolving science, commit to incorporating digital innovation, promote multidisciplinary training and care delivery, and empower patients to decide on appropriate use of their data.

The willingness to address shortages of cancer medicines and vulnerabilities in the supply chain in partnership with all relevant stakeholders.

Supply chains are complex, globalised and their strength depends on a multitude of factors. By using the European Medicines Verification System's (EMVS) data repositories to monitor medicine shortages, we can understand the root causes of shortages. Building better supply security will require a risk-based approach, the development of a list of essential medicines for which supply monitoring would apply, a common definition of shortages, as well as greater clarity on when a shortage should be notified to the authorities.

A collective willingness to address inequalities and barriers to patient access.

As an industry we have a dual responsibility: to ensure patients get access to innovative treatments and to deliver the next generation of treatments – both for patients who currently have no treatment options and those who can have their outcomes improved. Bringing critical medicines to the market faster, by using new data generation opportunities and novel endpoints with convergence between regulatory, HTA and payer bodies can help address delayed or unequal patient access, which currently results from many factors beyond companies' decisions (e.g. local health priorities, national budgetary decisions, hospital formulary decisions, investment in health infrastructure). It is vital to involve all stakeholders and come to a shared understanding of the root causes of barriers and delays to access, and most importantly to co-create solutions.[7]

Relevant and up-to-date national cancer plans and mechanisms to measure progress.

There is a need for a Measurement Matrix framework to assess progress in cancer care through tools such as the IHE Comparator Report toolkit. This will help to keep all stakeholders involved in cancer care accountable and ensure continuous progress, complementing the Cancer Inequalities Registry of the Europe's Beating Cancer Plan, making full use of innovative digital and data tools for timely data sharing.[8] Europe's Beating Cancer plan should support National Cancer Plans, facilitating the sharing of best practice among Member States, complementing national initiatives and filling gaps.

Innovation is transforming outcomes and quality of life of patients and survivors. The only way to fulfil the commitment to save 3 million lives by 2030 is to implement and adapt to what we know now, by integrating what we have learnt during the pandemic to make a difference for cancer patients.

[1] https://www.efpia.eu/about-medicines/development-of-medicines/intellectual-property/
[2] https://www.efpia.eu/about-medicines/development-of-medicines/regulations-safety-supply/efpia-regulatory-road-to-innovation/
[3,4] https://www.efpia.eu/media/636486/improving-regulatory-timelines-to-optimise-patient-access-to-innovative-oncology-therapies-in-europe.pdf
[5] Vintura (2020), Everyday counts – Improving time to patient access to innovative oncology therapies in Europe: https://www.efpia.eu/media/578013/every-day-counts.pdf
[6] EFPIA (2021), Statement on adoption of Health Technology Assessment Regulation, https://efpia.eu/news-events/the-efpia-view/statements-press-releases/efpia-statement-on-adoption-of-health-technology-assessment-regulation/
[7] https://www.efpia.eu/about-medicines/use-of-medicines/disease-specific-groups/fighting-cancer/for-patients-every-day-counts/
[8] IHE Comparator Report toolkit (2020), https://www.efpia.eu/publications/cancer-comparator-report/