To: Ms. Stella Kyriakides, European Commissioner for Health and Food Safety
Mr. Margaritis Schinas, Vice-President for Promoting our European Way of Life
Mr. Thierry Breton, European Commissioner for Internal Market
Ms. Margrethe Vestager, EVP and European Commissioner for Competition

16 March 2023

Subject: Cancer patients need a patient-centered and fit for purpose pharmaceutical system

Dear VP, EVP, and Commissioners,

As a group of non-profit organisations working tirelessly to make innovative cancer treatments with proven added value swiftly available to every European patient in need, we appreciate the European Commission's work done so far to beat cancer in Europe.

The revision of the EU pharmaceutical legislation is an opportunity to address unmet medical needs and ensure timely access to safe, effective, and affordable medicines for all patients who need them. We, therefore, call on the European Commission to present its legislative proposal without further delay.

Meanwhile, we would like to draw your attention to a few important elements that should be prioritised during the revision.

To incentivise innovation around unmet medical needs, opportunities for non-profit entities, including academia, to develop medicinal products should be created. This can be done by introducing a separate market authorisation procedure tailored to specific needs of these entities. We also support the Commission's plan to provide a dedicated regulatory, procedural, and administrative support for not-for-profit developers of medicines.

To guarantee that new treatments are developed for patients with high unmet needs, it is important to provide a clear definition of products that address such needs. The following criteria are key for defining unmet medical needs: absence of satisfactory treatment authorised in the EU and seriousness of a disease, and lack of access to an authorised treatment for patients across the EU.

We applaud the Commission's intention to reduce the current standard period of regulatory data protection. However, we think that such period should never be longer than 8 years with all conditional extensions included (product addressing unmet medical need, conduct of comparative clinical trials and launch of the product in all Member States etc.). If Europe wants to reward real breakthrough drugs and access to these drugs, the standard period should be reduced to 4 - 5 years, while the additional periods need to be extended. Extra data protection for transparency on cost should be introduced (for example, on disclosing all relevant public funding received for research and development). This way, we will get truly innovative and accessible treatments which will create a competitive European market.

We are very concerned about the Commission's intention to introduce a transferable exclusivity voucher to incentivise the development of new antimicrobials. We agree that incentives are urgently needed, but such a voucher could worsen the access to treatments for rare diseases or cancer. In this regard, we are aligned with the position outlined in the 'Non-paper: Novel stimuli for the development and keeping on the market of antimicrobials'.

In addition, medicine developers should take quality by design approach when conducting clinical trials and include endpoints such as overall survival and quality of life to provide a more robust evidence base to assess the effectiveness of new treatments and help decision makers along the value chain. To come up with the appropriate evidence for European Medicines Agency (EMA), health technology assessment (HTA) bodies and payers, a mandatory early dialogue on the design of the clinical trials that involves all these actors is needed. To have a faster reimbursement decision, EMA and HTA bodies should start to exchange information as soon as EMA receives an application for a market authorisation, so that the process of EMA happens in parallel with the HTA process.

Finally, we support the Commission's plans to prevent medicine shortages.

Our detailed recommendations are available here and here.

We look forward to the publication of the legislative proposal in March.

Signatories:

- The Association of European Cancer Leagues
- The Anticancer Fund
- The European Fair Pricing Network