Subject: [Name of your cancer society] and ECL recommendations for the pharmaceutical package

Dear Mr/Ms XX,

[Short intro to your cancer society, e.g., name and mission]

We are a member of the Association of European Cancer Leagues (ECL), a non-profit, pan-European umbrella organisation connecting 32 national and regional cancer societies in 27 WHO European region countries. Our organisations believe that the ongoing revision of the European pharmaceutical framework is an opportunity to make the pharmaceutical system patient-centred and fit for purpose by addressing unmet medical needs (UMN) and ensuring availability and timely access to safe, effective, and affordable medicines for all patients in need. To that end, we would like to share our recommendations on how this could be achieved.

As for the **pharmaceutical directive**, we support the following measures outlined in the European Commission's legislative proposal:

- The redesign of the **regulatory protection system** from 'one size fits all' to a modulated one in article 81 as it promotes patient access to affordable medicines across the EU and addresses the UMN. We particularly welcome the reduction of basic regulatory data protection period as this would allow cheaper generic and biosimilar medicinal products to enter the market faster and therefore substantially improve access to treatments.
- The establishment of a criteria-based **definition of UMN** to incentivise the development of medicinal products in therapeutic areas that are currently underserved in article 83. We believe that the European Commission has correctly identified key criteria for such definition, and welcome its further specification in implementing acts, considering scientific input by the European Medicines Agency (EMA). To ensure that the concept of UMN reflects scientific and technological developments and current knowledge in underserved diseases, we support the involvement of all pertinent stakeholders and patient organisations when adopting scientific guidelines by the EMA for the application of this article.

In addition, we are pleased that the position adopted by the European Parliament improves certain elements of the Commission's proposal and we invite you to support them as well:

- The requirement to **publicly disclose information on the authorisation, suspension or withdrawal of the hospital exemption (HE)** approvals in article 2. The HE plays a crucial role in providing timely access to safe, effective, and affordable treatments in cases when there is UMN and lack of interest from the industry, so we applaud better visibility on all available treatments prepared under the HE across the EU. In addition, we strongly support the **authorisation of the cross-border exchange** of treatments prepared under the HE as this guarantees the EU-wide patient access.
- Strengthened provisions on **transparency on R&D costs** related to medicines development, obliging companies to declare also the direct financial support received from not-for-profit organisations, as well as any indirect support received in article 57. This information, when provided in an easily accessible, full, and timely manner, can help national authorities in the price negotiations.

Finally, we invite you to improve the legislative text by **harmonising the application of the HE** in article 2 by:

- Providing a **definition of a 'non-routine basis'** concept, which should be centred around a treatment scale that is limited to the treatment capacity of the hospital. If the treatment

scale exceeds the capacity of a hospital, or multiple hospitals provide one treatment under several licences, a **transition period of 5 years should be offered to obtain centralised marketing authorisation** and possible decentralised manufacturing.

Regarding the **pharmaceutical regulation**, we support the following measures proposed by the Commission:

- Provision of **parallel scientific advice** to medicine developers given by the EMA and the health technology assessment bodies in article 59. This will help medicine developers generate clinical evidence that meets the needs of the different authorities along the medicinal products' life cycle, while respecting the different remits of the legal frameworks concerned.
- **Support scheme**, consisting of regulatory, procedural and administrative support and reduction, and the deferral or waiver of fees, **dedicated to SMEs and not-for-profit entities** in article 164 as they have an important role to play in the development of medicines.

Certain improvements to the Commission's proposal in the European Parliament's position are very appreciated and should be supported by the Member States, for example:

- Allowing not-for-profit entities to provide data on **repurposing existing medicines** to competent authorities, potentially resulting in new therapeutic indications of off-patent medicinal products and not limiting the repurposing to the areas of UMN but making it possible for all indications in article 48.
- Not restricting the provision of **scientific and regulatory support for priority medicines** to orphan medicinal products only in article 60.
- Extension of the provision of **protocol assistance and research support to the not-for-profit entities** in article 68.
- Mandating the Commission to facilitate **joint procurement** of centrally authorised drugs on the Member States' behalf upon their request in article 73 a (new). This is in line with one of the priorities for the next legislative cycle outlined in the ECL Manifesto 2024.

Finally, we do not support the introduction of a transferable data exclusivity voucher for new antimicrobials in articles 40 – 43, as it could be extended to rare diseases or oncological therapeutics and therefore further worsen access to these medicines. To that end, we recommend deleting articles 40 – 43. Development of antimicrobials should be supported by other types of incentives, such as direct financial incentives.

Our recommendations with concrete amendment suggestions are available here and here.

We also would appreciate an opportunity to meet with you to discuss this subject in more detail.

Thank you for taking our views into account. We remain available should you require additional information.

Kind regards,

[Your name]