ECL recommendations for the Critical Medicines Act

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Medicine shortages are an increasing problem in the European Union (EU). Shortages of oncology medicines pose a special challenge because cancer affects many people and because many oncology medicines have a narrow therapeutic window, meaning that these products cannot be easily substituted. Cancer medicines are one of the classes of medicines most affected by shortages and this can have great impact on the treatment of cancer patients [1, 2, 3].

The Association of European Cancer Leagues (ECL), a non-profit umbrella organisation uniting 34 national and regional cancer leagues, welcomes the proposed Critical Medicines Act to improve coordination among EU member states to leverage in full the EU's potential to strengthen the security of supply of medicinal products and ensure that each European patient has access to the medicines they need.

We believe that in certain areas the draft Regulation can be improved and set out our recommendations below.

Financial support for strategic projects (Articles 15 and 16)

While we support the designation of strategic projects, we are concerned that the proposed Regulation lacks measures obliging the undertakings that benefited from national or EU funding to supply medicines to the EU market in quantities needed and at affordable and transparent prices. We call on the co-legislators to add such requirements.

To avoid situations where manufacturers located in certain member states produce predominantly for the domestic market of that member state, a clarification of EU market prioritisation for supply and "very best efforts" to ensure availability of the critical medicinal product across all member states where it is marketed is needed in Article 15(2). In addition, it should be clarified in Article 15(3) how member states that have provided funding to strategic projects are expected to act when the companies they supported receive requests from other member states to provide medicinal products for their markets. Currently it is not clear if such requests can be turned down and what happens in such situations.

We fully support the possibility to provide EU funding to facilitate investments in strategic projects (Article 16). However, such support should be adequate and not limited to the current Multiannual Financial Framework, otherwise, there is a risk that reshored manufacturing capacity will be concentrated in those member states that are able to subsidise new production sites, or those that already have strong pharmaceutical industry. This, in turn, could lead to logistical challenges as well as market imbalances when member states with established pharmaceutical industries become stronger while those without such capacity are left weaker and more dependent on imports. Additionally, there could be a risk that, when facing a shortage

situation, individual member states prioritise production for their own domestic markets, rather than for the EU market.

In addition, EU funding should be prioritised for strategic projects in member states with smaller populations, where domestic demand will be more easily met, allowing production to be redirected sooner to supply other parts of the EU. This would reduce debates about what constitutes a fair distribution of products and ensure that, particularly in emergency situations, more medicines reach the EU market faster and more equitably.

Where member states with larger population sizes receive EU funding for strategic projects on their territory, this funding should be conditional on the member state's legally binding commitment to making product available to the entire EU market in sufficient quantities. Stipulations could include a percentage split (e.g. 20% for domestic, 80% for the EU market), a model based on reaching a certain population threshold (e.g. once 20% of the population have access to product, the rest needs to go to the EU market until 20% of Europeans have access), or a combination of both. Agreeing on these terms beforehand can prevent debates when there are emergency shortages or public health threats.

Public procurement procedures (Articles 18 and 19)

Patients face unacceptable delays and inequities in access when vital medicines are withheld by opaque procurement practices or fragmented national responses. We call for more transparency among contracting authorities and EU-level coordination. Transparency on the public procurement results regarding stock data, pricing and other critical information would help to identify shortages earlier and allow for more coordinated and effective response across the EU.

Contingency stocks (Article 20)

The obligations imposed by some member states on companies to hold contingency stocks have created knock-on effects in other member states, especially smaller ones, by distorting supply flows. We therefore call for harmonisation of such requirements across the EU and their extension to all companies supplying critical medicines in respective member states. To ensure fairness and stability across all EU countries, companies should guarantee the supply for a certain harmonised minimum period.

Also, the European Commission should be given a central role in developing a common strategy on stockpiling, and consideration should be given to establishing an EU-wide reserve to facilitate the sharing of medicines in times of crisis.

Collaborative procurements (Articles 21 - 24)

We strongly support the collaborative procurement options as proposed by the European Commission. Collaborative procurement can help achieve lower prices and make small markets attractive for suppliers, offsetting current inequalities among the EU member states and tackling shortages. It can also guarantee equitable access to new medicines with proven added value in all European countries.

We particularly applaud the use of collaborative procurements for medicinal products of common interest, meaning medicines that are not available in three or more member states in quantities and presentations needed to cover the needs of all patients. This mechanism could help accelerate access to new medicines, such as treatments for rare cancers, where central authorisation is granted but the product is not yet available in all member states. We call on the co-legislators to maintain the scope of collaborative procurements as proposed by the Commission and not limit it to certain medicinal products only.

In addition, the collaborative procurements should be made as accessible as possible. We therefore call for a lower minimum threshold of participation in joint procurement, currently set at nine member states in Article 23.

Critical Medicines Coordination Group (Articles 25 and 26)

We support the establishment of the Critical Medicines Coordination Group to facilitate the implementation of the Regulation and call for the inclusion of representatives of patients and healthcare professionals in said group. Their practical knowledge is essential to ensure that measures proposed by the CMA reflect the specificities of healthcare systems.

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References

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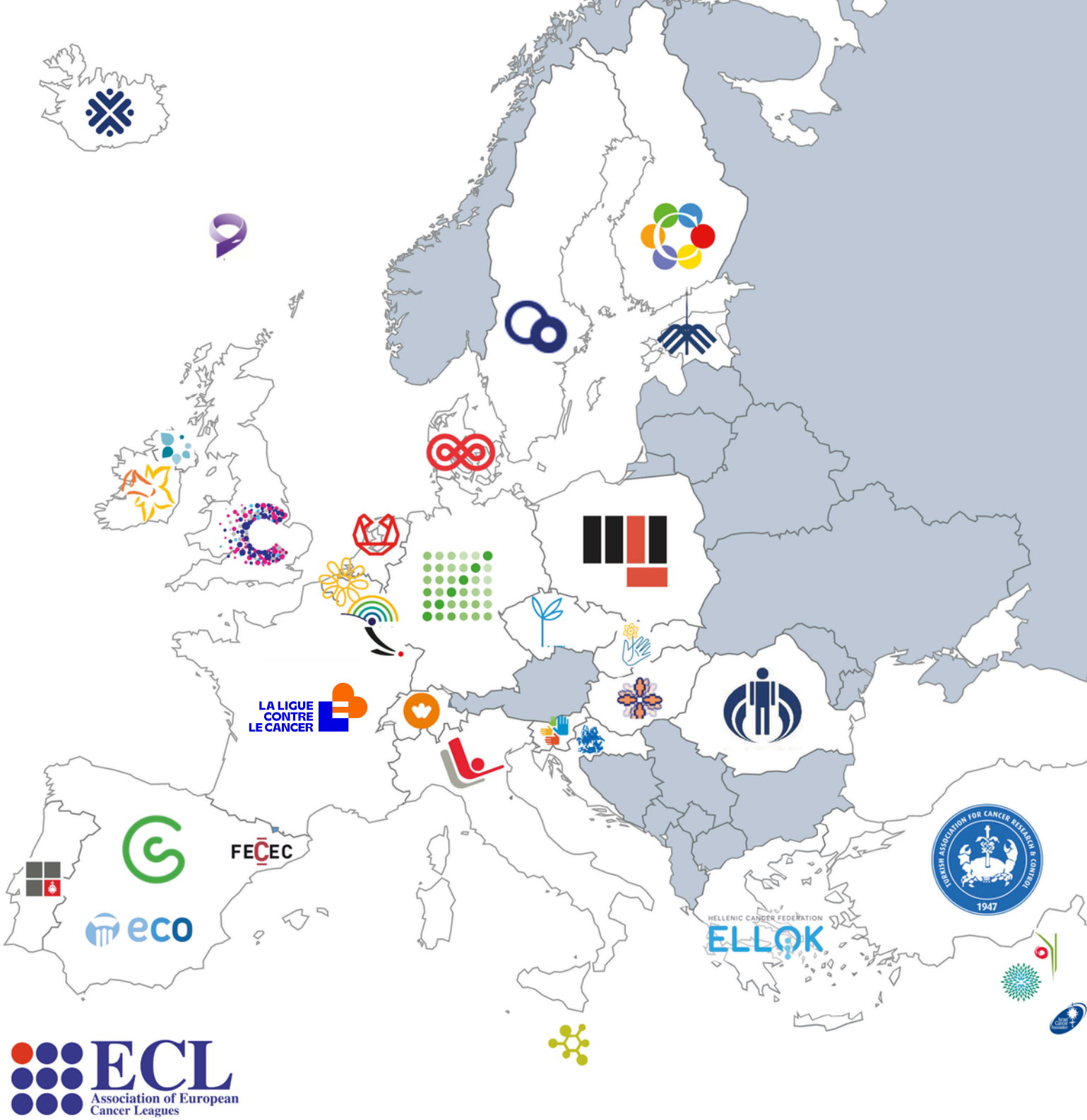

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Association of European Cancer Leagues

The **Association of European Cancer Leagues (ECL)** is a non-profit umbrella organisation made up of 34 national and regional cancer leagues advocating for improved cancer control and care across Europe. Our vision is a Europe free of cancer.

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