JOINT STATEMENT ON HOSPITAL EXEMPTION IN EU PHARMACEUTICAL DIRECTIVE

1 October 2025

We welcome the adoption of the Council's general approach on EU pharmaceutical legislation and the launch of trilogue negotiations. As civil society organizations, researchers, and health advocates, we call on co-legislators to harmonize the Hospital Exemption (HE) as current divergent national laws hinder export and thus prevent equitable access to advanced therapies developed in public and non-profit settings.

The Council's position includes notable improvements, such as clearer requirements for data reporting. Nevertheless, we remain concerned that important safeguards are missing. The current proposal fails to provide support for academic or non-profit developers to comply with the regulatory requirements. It also does not create any route for cross-border access — which is essential to ensure equitable access for patients in smaller or less-resourced Member States. There is still no commitment to making hospital exemption data or information on costs and pricing publicly available, which undermines transparency.

We believe the ongoing negotiations should reflect and uphold important public interest provisions, such as the inclusion of support mechanisms for academic and non-profit institutions, the establishment of a public and regularly updated data repository, the possibility of cross-border use, the harmonization of data collection processes, and the evaluation of clinical evidence. These measures are essential to ensure that the hospital exemption works consistently across EU Member States, supporting equitable access for patients, and ensuring transparency and accountability.

We also support the initial clarity provided by the European Commission regarding the scope of the hospital exemption, and we caution against approaches that would restrict the use of the hospital exemption based on existing commercial competitors, among others.

We urge the trilogue negotiators to reflect this in the final text. The Hospital Exemption must be a legally robust, equitable tool—not a last resort, but a complementary path to innovation and access.

Signed,

SALUD por DERECHO
Right to health foundation

ECL
Association of European Cancer Leagues

eha

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