STAKEHOLDERS CALL FOR PROTECTION OF THE HOSPITAL EXEMPTION

19 February 2024

The revision of the European Union's pharmaceutical legislation, proposed by the Commission in April 2023, sets out to ensure that all patients across the EU have timely and equitable access to safe, effective, and affordable medicines. The hospital exemption (HE), codified in Article 2 of proposed Directive 2023/0132(COD), provides a substantial contribution to this aim.

Signatories of this statement call for the protection of the hospital exemption, ahead of the ENVI Committee vote. Several amendments have been tabled, including by the rapporteur, which severely narrow the scope of Article 2 and threaten the provision's usability and impact.

HE constitutes an indispensable complement to the commercial pathway, in order to fill the gaps left by industry, and should not be construed by lawmakers as a circumvention of the marketing authorization process. Commercial development of these innovative therapies is often not viable for pharmaceutical companies, due to insufficient return on investment and small patient populations. This is proven by the fact that industry is less involved in ATMP development than in the development of conventional medicines; in fact, commercial development of ATMPs is highly dependent on public funding. (1)

We want to emphasize that the hospital exemption is a vital recourse for patients requiring personalized treatment and/or battling (ultra) rare diseases, whose medical needs cannot otherwise be met. Article 2 also reflects the reality that many ATMPs stem from clinical practice and are formulated closely to the patient.

HE approvals entail careful consideration by the Member State competent authorities, as permits are only accorded to ATMPs which foresee a benefit for the patient, meet regulatory requirements and are not inferior to the standard of care. To that extent, any limitations on the use of HE should be carefully evaluated and be kept proportional:

- The duration requirements of a hospital exemption cannot lead to the interruption or unavailability of patient treatment, nor create an unnecessary administrative burden for HCPs that takes away from patient care or slows decision-making.
- HE should not be confined to cases where no medicine for that indication is approved (at EU level), as approval does not always translate to availability and access. ATMPs are often not available due to the marketing strategies of marketing authorization holders, high prices, or negative reimbursement decisions.
- Clinical trials or compassionate use programs for a similar indication cannot qualify as reasons for not granting a hospital exemption approval. There is no guarantee that the medicinal product being studied will actually be approved, nor that the patient can be included in the clinical trial in question; moreover, the final indication might be of narrower scope than initially foreseen.

To conclude, a legal framework on hospital exemptions is fundamental in order to create legal certainty, remove disparities between Member States, and create the highest possible benefit for patients. HE should be available to every patient that needs it. In addition to improving access, the hospital exemption contributes to the sustainability and resilience of national health systems.