

EuropaBio response to public consultation on the evaluation of patient rights in cross-border healthcare

EuropaBio sees the Directive on cross-border healthcare as an important instrument to ensure patient access to the best available care. The Directive is particularly relevant for advanced therapies and medicines for rare diseases. Cell and gene therapies require highly specialised physicians and hospitals working in networks of reference centres. For rare diseases with limited patient numbers, it is impractical for each Member State to have a dedicated treatment centre. Well-functioning EU cross-border healthcare legislation can ensure patients have access to specialised treatments and novel therapies when these are not available in their home country. EuropaBio has identified the following challenges for accessing care abroad, and recommendations for improvement:

- Approval timelines for cross-border treatment are sometimes very long; they should be capped.
- In many countries, the approval process is opaque with no possibility to appeal denials. The process should be more transparent and open to patient representatives.
- Where a Member State does not have a treatment centre, cross-border treatment of rare diseases should get a defined and accelerated pathway for approval. Pan-EU funding would help, or accelerated reimbursement once a rare disease therapy is available in enough Member States.
- Many hospitals discriminate against cross-border patients with mark-ups on the fees charged to local patients. This practice should be banned.
- Hospitals often need to wait months or years for reimbursement and face significant budget impact when not paid. Such disincentives for treating cross-border patients should be eliminated and mechanisms to allow innovative payment models to function across borders implemented.
- Healthcare providers often do not know how to request reimbursement for cross-border treatments and ask therapy developers for support. Some Member States refuse reimbursement for treatments not available domestically. Better and practical information should reach all stakeholders (HCPs, patients, companies, social security entities) to secure the best treatment.
- Difficulties in cross-border participation to clinical trials despite high need remain barriers to innovation. Reliable and accessible information is needed, e.g. through multi-stakeholder, multi-national recommendations with information about existing options and best practices. Establishing Europe-wide patient registries to facilitate long-term patient follow-up would help.
- Due to the upfront payments imposed by the Directive, cross-border treatment with advanced therapies appears possible only through the 'S2 route'. Patients cannot bear the total costs of their treatment and subsequently seek reimbursement. Processing timelines for obtaining prior authorisation using the 'S2 Form' vary greatly. Alignment across the EU is needed.



- Difficulties in approving advanced therapy applications if not reimbursed in the home country despite being reimbursed in the country of treatment should be addressed. Special access funds should be allocated to countries with restricted budgets. EU guidelines on which advanced treatments should be approved to ensure harmonised access across EU would be helpful, with clarification on process for prior authorisation, clear timelines for decision making and reimbursement.

The EU Pharmaceutical Strategy for Europe has identified unequal access to care as one of the most significant healthcare challenges for the EU. EuropaBio believes that proper implementation of the EU Cross-border Healthcare Directive would go a long way to address this problem.

The COVID-19 crisis has shown that Member States can work together to provide efficient patient care across borders. The Commission stimulated cross-border treatment of Covid-19 patients through issuing facilitating guidelines in 2020. If the same spirit of collaboration were applied to cross-border healthcare in general, it would help ensure all EU patients have equal access to novel treatments.

