

EuropaBio's response to the EC consultation on patients' rights in cross-border healthcare

NEWS RELEASE

Brussels, 20 July, 2021 – EuropaBio responded to the European Commission's (hereafter, EC) [Public consultation](#) on the **Directive 2011/24/EU on patients' rights in cross-border healthcare**. The Directive sets out the conditions under which a patient may travel to another EU country to receive medical care and reimbursement. The EC aims at assessing whether the EU rules give patients access to safe and high-quality healthcare in another EU country and encourage cooperation between national healthcare providers, also on rare diseases and European Reference Networks.

EuropaBio, representing biotechnology and biopharmaceutical medicine developers sees the EU legislation on cross-border healthcare as an important instrument to ensure patient access to the best available care.

EuropaBio believes, that sometimes, the approval timelines for cross-border treatment are long. In many countries, the approval process is opaque with no possibility to appeal denials.

When it comes to the fees, many hospitals discriminate against cross-border patients with mark-ups on the fees charged to local patients. Also, very often hospitals need to wait months or years for reimbursement and face significant budget impact when not paid. This creates a disincentive for treating cross-border patients.

There are also difficulties in cross-border participation to **clinical trials**. Due to the upfront payments imposed by the Directive, cross-border treatment with advanced therapies appears possible only through the 'S2 route' that is difficult to apply and not aligned in all Member States.

For many **rare and complex genetic diseases**, the treatment of EU patients abroad is often the only option. As the number of patients can be extremely limited, it is not possible to have a dedicated treatment centre in each Member State. For this reason, a well-functioning EU cross-border healthcare legislation is crucial to ensure patients' access to specialised treatments and novel therapies when these are not available in their home country.

Proposals for improvement

- Capped approval timelines for cross-border treatment.
- More transparent approval process for reimbursement requests, which is 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.
- Banning the practice of many hospitals to discriminate against cross-border patients with mark-ups on the fees charged to local patients.
- Mechanisms to allow innovative payment models to function across borders should be implemented.



- Better and practical information should reach all stakeholders (HCPs, patients, companies, social security entities) to secure the best treatment.
- Reliable and accessible information is needed on cross-border participation to clinical trials, e.g. through multi-stakeholder, multi-national recommendations with information about existing options and best practices.
- Establish Europe-wide patient registries to facilitate long-term patient follow-up.
- Processing timelines for obtaining prior authorisation using the 'S2 Form' should be aligned across the EU. The time it takes to obtain a prior authorisation for the treatment of rare diseases should be particularly shortened to meet the high needs of rare disease patients.
- Specific funds should be allocated to countries with restricted budgets in particular as regards access to novel advanced therapies. 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.
- Improved HTA coordination to avoid multiple submissions and enable patient access.

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.

Please find EuropaBio's full response to the Consultation here (to be included after July 27).

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About EuropaBio

EuropaBio, the European Association for Bioindustries, promotes an innovative and dynamic European biotechnology industry. EuropaBio and its members are committed to the socially responsible use of biotechnology to improve quality of life; to prevent, diagnose, treat, and cure diseases; to improve the quality and quantity of food and feedstuffs and to move towards a biobased and zero-waste economy. EuropaBio represents corporate and associate members, plus national biotechnology associations and bioregions.

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