Enabling Patient Access to Transformational Therapeutic Innovations: Modernising the EU's Cross-Border Healthcare Framework

In the EU, citizens have a right to access healthcare in any EU country and to be reimbursed for care abroad by their home country. Over the last two decades, through legislative interventions and judicial decisions, the EU has built a cross-border healthcare framework that is intended to facilitate citizens' exercise of this right. Directive 2011/24/EU (Cross-border Healthcare Directive) and Regulation (EC) No 883/2004 (Coordination of Social Security Regulation) govern the rules and procedures of what are intended to be two complementary pathways to cross-border healthcare.

For patients whose treatment involves Advanced Therapies Medicinal Products (ATMPs) that can only be administrated in specialised centres, cross-border healthcare is often the only, albeit complex, way to access these transformative therapies. The product characteristics of many ATMPs, their administration procedures, and the required infrastructure and skilled workforce inherently limit the close geographical availability of such therapies for patients. Better access to ATMPs in Europe is dependent on a well-functioning cross-border healthcare framework.

On 12 May 2022, the Commission published the first evaluation of the Cross-Border Healthcare (CBHC) Directive more than ten years after its adoption.[1] The evaluation highlighted the many issues surrounding the Directive as well as the many barriers that patients seeking healthcare across borders face. Most importantly, the evaluation concludes that while the Directive has been partly successful in delivering on its objectives to a certain extent, its full potential has not been realised.

EuropaBio considers that the evaluation of the Directive is a first step in a larger review process of the cross-border healthcare framework that can improve access at the patient level rather than the country level. Removing the barriers to cross-border healthcare in Europe has the potential to enable patients access to life-saving therapies regardless of their country of residence.

[1] European Commission (May 2022), REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (COM(2022) 210 final) and COMMISSION STAFF WORKING DOCUMENT Accompanying the document REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (SWD(2022) 200 final).

EuropaBio *aisbl*
Avenue des Arts 53, 1000 Brussels
+32 2 735 03 13
www.europabio.org
VAT BE0477520310

Recommendations

The EU cross-border healthcare framework is placing a disproportionate burden on patients requiring innovative therapies due to its complexity and inadequacy to meet their needs. Lack of information, high upfront payment for healthcare costs and uncertainty over reimbursement, and complex administrative barriers are faced by cross-border patients and carers which add to the burden of their condition.

EuropaBio believes that significant improvements, including legislative, to the EU's cross-border healthcare framework are necessary to ensure it meets patients' needs when it comes to access to innovative treatments. Guaranteeing simpler and wider access to care at patient level is where the EU can bring significant added value from integration and collaboration.

Building on the expertise of its members in the fields of orphan medicines and ATMPs, EuropaBio recommends the following actions to create a harmonised and easy-to-use cross-border healthcare framework that works for patients:

- Calls upon the Commission to convene a structured dialogue with the Member States and other stakeholders to ensure better functioning of the Directive during the implementation of the 11 non-legislative actions presented alongside the evaluation.
- Harmonise and cap processing time of requests for prior authorisation and reimbursement, in particular for patients with rare diseases.
- Maximise the value of European Reference Networks (ERNs) and take them to the next level. The ERNs should have the appropriate resources and mandate to provide advice, support, and guidance to patients seeking specialised care outside their home country.
- Improve the transparency of the approval process for reimbursement requests.
- Create an EU funding mechanism to support cross-border access to innovative treatments such as ATMPs or orphan medicines in cases where a Member State does not have a treatment centre.
- Establish Europe-wide patient registries to facilitate long-term patient follow-up.
- Consider withdrawing the current proposal for a revision of the Regulations on the coordination of social security systems and present a new proposal for a Regulation that would also amend the CBHC Directive to ensure the coherence and complementarity between the two cross-border healthcare pathways.

EuropaBio *aisbl*
Avenue des Arts 53, 1000 Brussels
+32 2 735 03 13
www.europabio.org
VAT BE0477520310

A patient's complex and expensive cross-border healthcare journey

In seeking specialised care across borders, patients and their carers must contend with complex administrative procedures and significant costs which only add to the burden of the disease. Most strikingly, the evaluation of the CBHC Directive showed that the barriers and costs are disproportionately placed on patients from lower-income countries, patients with lower economic status, or patients requiring access to more expensive highly specialised treatment, such as patients with rare diseases, being most affected.

This is contrasted by the fact that the overall costs including reimbursement and treatment under the Directive are minor and the financial impact on national healthcare budgets has been minimal.

Patients need to determine what rules, from the Directive or the Regulation, apply to their case. Such is the complexity of the cross-border healthcare framework that even National Contact Points (NCPs) and health insurers have difficulties informing patients. The situation has led stakeholders, in particular patient organisations and the industry, to fill the gaps by providing their own guide to receiving cross-border healthcare. As revealed by the evaluation, some patients have also retained the services of private contractors to assist them in seeking cross-border healthcare.

ATMPs are complex products that must follow rigorous and complex manufacturing and treatment processes contrary to more traditional medicines.[2]

The process for the production of ATMPs requires equipment, know-how and appropriate facilities. The four main activities required for tissue/cell transformation from a donor to a treatment for a recipient: 1) Donor supply: donor location, informed consent, donor eligibility, tissue/cell removal; 2) Control: virological and bacteriological testing; 3) Treatment and storage: the transformation of tissues/cells into a product ready for application as a treatment to the recipient; 4) Distribution: for sending the final product to the clinician or hospital where the tissue/cell will be administered to a patient.

In some cases, products have very limited shelf lives of less than half a day and patient monitoring after treatment require follow-up visits with the treating physician for as long as a month.

[2] Goula, A., Gkioka, V., Michalopoulos, E., Katsimpoulas, M., Noutsias, M., Sarri, E. F., Stavropoulos, C., & Kostakis, A. (2020). Advanced Therapy Medicinal Products Challenges and Perspectives in Regenerative Medicine. *Journal of clinical medicine research*, 12(12), 780–786. https://doi.org/10.14740/jocmr3964

Cross-border healthcare through the Regulation requires significant planning from patients and their carers to deal with complex administrative procedures which can vary from one country to the next. Patients need to request a treatment plan from their physician, gather information from their insurers and NPCs, request an application for an S2 form, complete the S2 form and submit the required paperwork, gather information on travel and make the necessary preparations, receive treatment, and finally re-join their country's healthcare system.

Under the Directive pathway, patients are faced with high upfront payment for healthcare costs, incoherent use of prior authorisation, complex administrative procedures, and uncertainty over reimbursement and information to patients.

For patients seeking treatment with ATMPs, there are difficulties in receiving approval if these therapies are not reimbursed in the home country, despite being reimbursed in the country of treatment.

Patients face high out-of-pocket costs for their treatment, the costs of travelling and accommodation abroad, costs related to administrative procedures, including postage or translation of medical records, as well as significant delays in prior approval and reimbursement. The time required to process prior authorisation requests varies from 14 to 69.5 days. Processing time for reimbursement ranges from three weeks to six months with or without prior authorisation. The "S2 form" route also includes uncovered additional costs on patients and their carers in relation to travel and accommodation, food, translation, or insurance.

Patients also face barriers after the delivery of care after a long and intense specialised treatment. For a patient that has been treated abroad, this becomes complicated from a logistical and care point of view (e.g., regular follow visits in the specialised treatment centre, meaning regular travel, longer hospital stays abroad, over a long period).

This process is very taxing on the patients and carers and the issues are particularly affecting patients seeking treatment with advanced therapies medicinal products (ATMPs), such as gene therapy, for which the framework is currently inadequate due to the high costs of the treatment and the need for centres of excellence, few of which exist as they require operational excellence and trained healthcare providers.

European framework on cross-border healthcare

The EU's framework for cross-border healthcare is composed of two main legal acts: Regulation (EC) No 883/2004 and Directive 2011/24/EU. The two acts are intended to establish complementary pathways to cross-border healthcare which require patients to navigate a maze of administrative procedures.

	Directive 2011/24/EU	Regulation (EC) No 833/2004
Type of healthcare provider	Public and private healthcare providers	Public healthcare providers only
Payment for cross-border healthcare services	Payment upfront for the healthcare services used with partial or full reimbursement afterwards	Entitled to healthcare in another EU/EEA country under the same conditions and at the same cost as people insured in that country
Reimbursement of costs for cross-border healthcare	Reimbursement to be claimed from patient's health insurance institution, up to the level that would have been paid in the patient's country of residence	Reimbursement between the institutions of the countries involved, based on the conditions and reimbursement rates of the country of treatment. If the patient has borne the cost of treatment, request for reimbursement can be made either in the country of treatment or country of residence
Price for healthcare	Private healthcare providers and, in certain cases, public healthcare providers are allowed to set their own prices or apply "private" prices for your healthcare as for a domestic patient (no discrimination)	Prices charged are the same as for persons covered by the social security system of the country of treatment
Prior authorisation	Not required in principle but may be requested by the country of insurance for certain treatments and equipment. Necessary in many EU Member States	Prior authorisation is always required for reimbursement of planned healthcare (S2 form)

In 2016, the Commission adopted a proposal to revise Regulation (EC) No 883/2004 to modernise the rules and ensure that they are fair, clear, and enforceable.[3] As of 2022 and after 17 trilogues between the Council, the

[3] European Commission (December 2016), Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 883/2004 on the coordination of social security systems and regulation (EC) No 987/2009 laying down the procedure for implementing Regulation (EC) No 883/2004 (COM(2016) 815 final).

European Parliament, and the Commission, the proposal remains unadopted following the rejection of two provisional agreements by the Council.

In practice, the Directive remains an underused and inconsistent pathway to cross-border healthcare in Europe. In 2019 290.890 patients received care abroad under the CBHC directive. Ten countries reported fewer than 20 requests in 2019 for prior authorisation under the CBHC directive. Only 23 cases – or 0.008% of those patients – of cross-border healthcare for highly specialized care were approved under the Directive from 4 different countries (Belgium, Denmark, Italy, and United Kingdom). [4]

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 79 corporate and associate members and bio-regions, and 19 national biotechnology associations in turn representing over 2300 biotech SMEs. Read more about our work at www.europabio.org.

[4] European Commission, Member State data on cross-border patient healthcare following Directive 2011/24/EU for the year 2019 (available here), p. 27.