

EuropaBio Advanced Therapies Series | Treatment Without Borders: The EU Case for Equitable Patient Access to Advanced Therapies

NEWS RELEASE

Brussels, 8 September 2021 - Advanced therapies have ground-breaking therapeutic potential, particularly in disease areas where there is an unmet medical need and available therapeutic options are inadequate or simply do not yet exist.

A key aspect of the EU Pharmaceutical Strategy seeks to improve patients' access to therapies for challenging and rare conditions across Europe. An important instrument, EU legislation on cross-border healthcare sets out a framework to ensure patient access to the best available care. In the context of reviewing the directive, however, we have the opportunity to improve the ability of EU patients to access novel advanced therapies and medicines for rare diseases when these are not available in their home country.

To better discuss avenues for enhancing the access of EU patients to novel biotechnology-derived treatments, EuropaBio launched a series of events, holding its second Advanced Therapies Series' webinar '**Treatment without borders: the EU case for equitable patient access to advanced therapies**' on 7 September 2021.

The first part of the discussion welcomed **Jana Popova**, Executive Committee Member of the European Alliance of Neuromuscular Disorders Associations and EUPATI Patient Engagement Training Coordinator. Jana presented recommendations on how to ensure better access to treatments outside their home countries:

- development of guidelines (by the European Commission) to disseminate information on the potential of the Cross-Border Healthcare Directive (CBHC), relevant National Contact Points (NCPs) and patient involvement;
- the development of a platform that provides information about CBHC;
- stronger cooperation among healthcare institutions in the Member States;
- an increased effort to overcome health inequalities between Member States and establish networks of support;
- the harmonisation of methods to engage with NCPs;
- the establishment of a position of patients' ombudsman, in charge of monitoring of the patients' rights.



The webinar continued with a panel discussion among EU, national, and industry representatives who put forward possible solutions for securing equitable access to both specialised centres and to treatment for all EU patients in need.

Martin Dorazil, Deputy Head of Unit Digital Health, DG SANTE, European Commission, informed us that the EC is monitoring the approaches implemented by the Member States, the effectiveness of these processes, and the barriers that patients still face, when seeking healthcare across borders.

An important part of the evaluation is to look at how the treatment and diagnosis of patients with rare and complex diseases have benefitted from the support of the European Reference Networks (ERNs) – networks of highly specialised healthcare providers across the Member States dealing with patients with complex rare diseases, aimed at facilitating the clinical collaboration between the healthcare providers

“ERNs should be the focal points for cooperation on research and innovation on rare diseases, on education and training of professionals”.

Irina Grossenbacher, Region Europe Patient Access Director at Novartis Rare Diseases, pointed out that Europe still lacks a framework for these patients to be treated fast, also due to the long approval timelines for cross-border treatments and the hospitals' “discrimination” against cross-border patients.

“EU institutions should discuss a pan European budget for cross-border treatments to enable equal access to all patients”.

Brieuc Van Damme, Director General, RIZIV/INAMI (the National Institute for Health and Disability Insurance), highlighted the importance of collaboration on patient registers, and the need to have robust evidence to improve scientific research and development. Mr. Van Damme also suggested that the mutual recognition of HTA reports may give patients quicker access to the therapies.

Dirk Vander Mijnsbrugge, Vice President Medical Affairs Lead Rare Diseases International Developed Markets, Pfizer, emphasised that the CBCH Directive should be reviewed taking into account the concepts of optimal care, early diagnosis and rapid intervention.

“CBCH directive revision is broader than simply securing access to novel treatments, it's also access to expertise”.

Tomislav Sokol, Member of the European Parliament, EPP, Croatia, concluded the discussion by advocating to strengthen the importance of merging the two sets of reimbursement tools and moving the reimbursement tool from the CBHC directive to the Social Security Coordination Regulation (given the Regulation is a much stronger legal instrument than the Directive, as it is directly applicable). Mr. Sokol also highlighted the urgency of removing the additional obstacles which are in the CBHC directive – one of the most important being the fact that it is the national experts who decide whether to give pre-authorisation or not, depending on whether there is a medical treatment available domestically.



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