A. Werbrouck[1], L. Schoonaert[1], T. Bols[2], A. Schuil[3], S. Vermeersch[1]. "Standardizing Cross-Border Access to Advanced Therapies." HPR143, 2023-11, ISPOR Europe 2023, Copenhagen, Denmark.

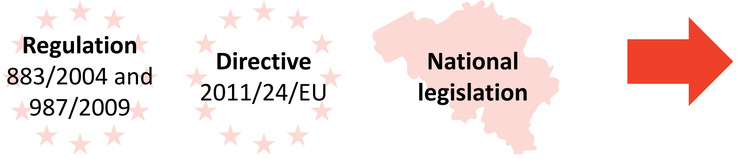
HPR143

Disclaimer: PTC Therapeutics and Orchard Therapeutics have promoted and supported the project financially and logistically. This work does not focus on specific diseases or treatments, including, but not limited to, those commercialized or under development by the supporting companies.

It will sometimes be inevitable for patients to travel abroad for Advanced Therapy Medicinal Products (ATMPs)

At this moment, many different issues related to planned cross-border healthcare hamper access

Legislative landscape is complex, and not fit for purpose

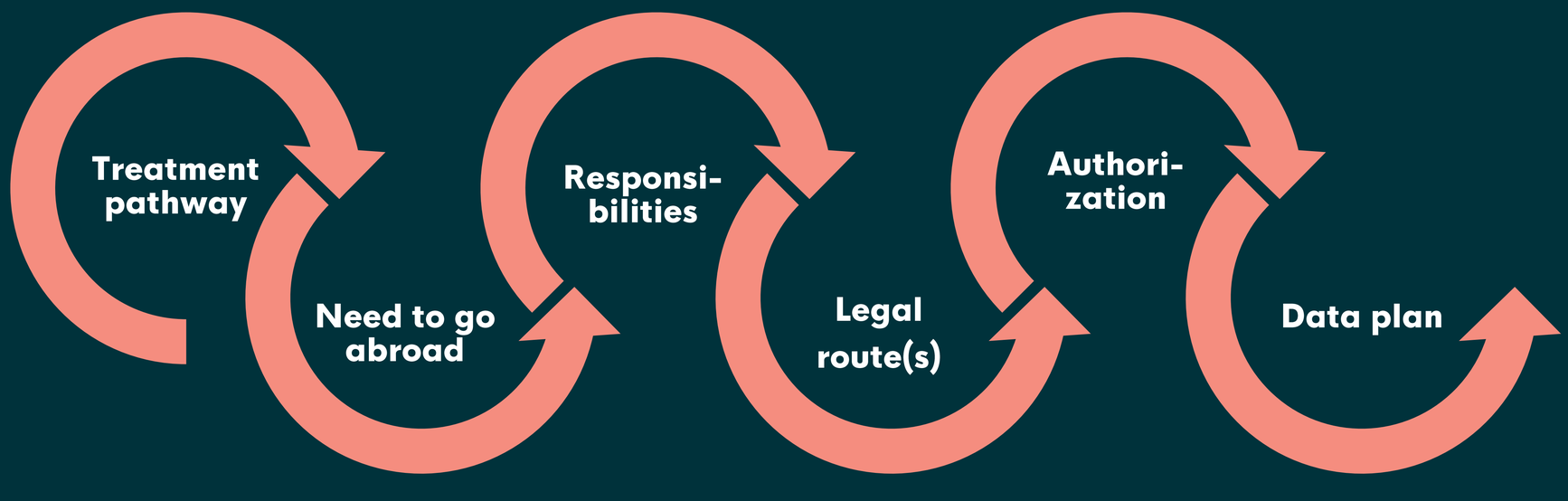


Depending on the particular context (country of residence, type of disease, reimbursement status of ATMP, …) several issues may hamper access

Related to **treatment** provided to the patient	Related to **financing** of medical and other costs	Related to **authorization procedure** for coverage of costs	Related to **data** for tracking and follow-up
Lack of uniformity of care can compromise quality of care More actors involved can induce additional ambiguous clinical responsibilities	Differences between countries in actual price, and VAT rates Unrealistic prepayment requirements for patients Confidentiality and practical implementation of managed entry agreements (MEAs)	Lack of a standardized approach leaves more room for unpredictable decisions Separate authorization requests for different aspects of care Patient as initiator can induce delays Time-consuming processes can make the patient ineligible for treatment	Systems to track the necessary data, specifically for each country, are not always in place Delays in data transfer can block payments, refunds, or negotiations

Cross-border healthcare involving ATMPs presents unique challenges

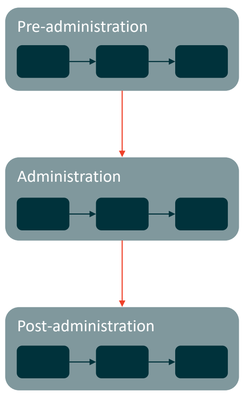
Standardization of the process can improve patient access



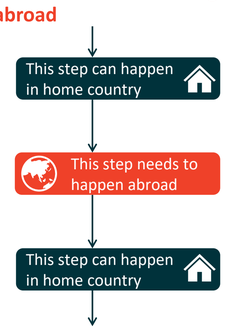
Our workflow to standardize the process bridges the gap between intent and practice

Standardization creates more transparency and predictability, and ultimately improves timely patient access to ATMPs beyond national borders:

1. Define the treatment pathway



2. Establish the need to go abroad



For each step separately

Iterative process, that can change over time

Encourage transfer of knowledge

3. Define responsibilities

Clinical

Product

Pharmaco-vigilance

Communication

Financial

…

4. Select the most suitable legal route(s)

Currently least feasible

Backpack method

Directive

National funds

Direct agreement

Regulation

Currently most feasible

5. Define a straight-forward authorization pathway

Centralized decision-making body

Predefined maximal period

Formal guidance and patient support

6. Set up a data plan

Different types of data

Data collector
Data owner
Data receiver

Track patient numbers: received approval vs. received treatment

Track patient outcomes: for follow-up vs. for MEA

This concept evolved through iterative co-development with different stakeholders

The **input and perspectives of different stakeholders** (patients, hospitals, physicians, industry, and payers) were collected to ensure the suggested solutions are feasible and can be implemented in practice. **Further iterations** with different stakeholders will be required for the practical implementation of our recommendations.

More?

Full report here:

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