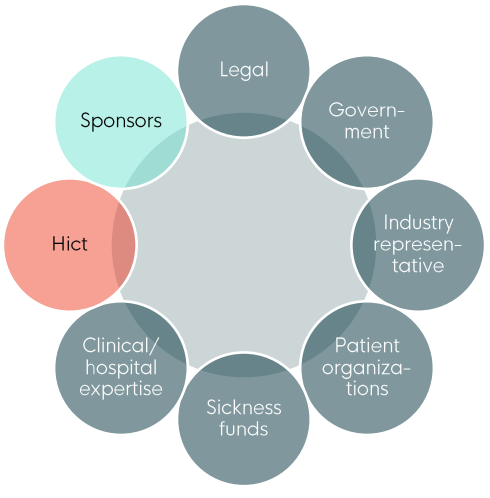
Cross-border healthcare for ATMPs:
A Belgian cross-stakeholder perspective



On 13 September 2022, a roundtable discussion was held in Brussels, Belgium. The discussion was moderated by prof. Stefaan Callens on behalf of Hict, held under Chatham House Rules.

The **objective** of the round table was to define what cross-border issues currently exist for ATMPs, and to identify what practical solutions or guidance can be offered to effectively address these issues within existing regulatory frameworks.

All participants agreed to limit the discussion to the **scope** of:

	Advanced therapy medicinal products (ATMPs)...	... that have been evaluated and approved for reimbursement in Belgium ...	...for which cross-border healthcare is required.
In scope	Gene therapy, somatic-cell therapy, tissue-engineered therapy, or combined ATMPs	Products seeking reimbursement in Belgium	Planned CBHC
Out of scope		Products not seeking reimbursement in Belgium, or issues related to early or fast access	Unplanned necessary CBHC, or CBHC for persons residing in other member state

... and agreed with the underlying **premise** that:

For patients, in as many ways as possible, the path they follow to get access to treatment should be no different for a product that requires them to cross borders than for a product that does not require them to cross borders.

Access to cross-border healthcare for ATMPs that have been accepted for reimbursement in Belgium should be without delay and not hampered by underlying barriers (e.g., budgetary or payment concerns, or complex approval processes) for any of the stakeholders involved.

Based on the remaining issues and proposed solution building blocks on the authorization process, cost coverage and macro-financial streams, a **list of minimal requirements** for a robust solution were proposed by the participating stakeholders:

Assure uniformity
Decisions of authorization in this context should be centralized.
Receiving authorization should not be dependent on a decision from one individual medical advisor.
Only a limited number of recognized referral centers should be authorized to file requests.
Include advice from international experts.
Develop clear criteria to grant authorization.
Assure affordability
Only those steps within the entire care pathway that cannot be provided in Belgium should be provided abroad.
For those steps within the care pathway that require treatment abroad, medical costs (care & cure) and travel- and accommodation costs should be covered.
One joint authorization request for all costs creates efficient use of resources.
A Belgian-specific product price, agreed upon during national reimbursement procedure, should be applicable for Belgian patients treated abroad.

Different **solution frameworks** were explored during the round table discussion, about which participants concluded that:

A **separate framework**, starting from a blank page, seems to be the most optimal framework to successfully integrate the minimal requirements for a robust solution.

- It was proposed to develop a container framework, providing a generic structure, that can be further tailored to each individual ATMP.

However, in parallel, it might be necessary to **foresee short-term temporary solutions** that builds on top of the Regulation.

- S2 requests in this context should be more streamlined by an on-top agreement or formal guidelines.

More information?

A detailed report of this roundtable discussion is available online.

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