"FROM PLANT TO PATIENT"

POLICY RECOMMENDATIONS TO SUPPORT A THRIVING ECOSYSTEM FOR ATMPS IN BELGIUM

Executive Summary

Introduction

Belgium's advanced therapy sector has been booming the last years. With its thriving life sciences ecosystem, boosted by highly skilled workforce and strong public-private partnerships in R&D, the country is well-positioned to unlock the full potential of advanced therapy medicinal products (ATMPs). As the advanced therapy market is expected to expand significantly over the next decade, Belgium faces concrete challenges that must be addressed to maintain its leadership. To explore solutions, Johnson & Johnson organized a multi-stakeholder debate on three critical pillars for bringing advanced therapies to Belgian patients: the supply chain, regulatory requirements and accessibility.

Key challenges

Despite its strengths, Belgium's ATMP ecosystem is under increasing pressure from global competition and structural hurdles. ***[Supply chain]*** Johnson & Johnson representatives highlighted that complex and fragmented regulatory procedures, especially those related to patient material imports, delay innovation and discourage investments. While Belgium boasts a highly skilled workforce they also emphasized that educational programs are not fully aligned with the evolving needs of the cell and gene therapy sector. High labor costs and the need for a stable, uninterrupted energy supply further undermine competitiveness according to an industry representative. ***[Regulatory requirements]*** A Johnson & Johnson representative pointed out that the lack of streamlined approval processes and harmonized contract templates, coupled with reduced agility under the EU Clinical Trials Regulation, has slowed clinical trial approval and diminished Belgium's attractiveness for global trials. Fragmented and unclear frameworks around GMO[1] authorizations create additional uncertainty, while academia raised concerns about financial and regulatory barriers to early clinical development under the hospital exemption pathway. Furthermore, academic stakeholders stressed that limited access to health data hampers efficient patient recruitment. ***[Accessibility]*** Johnson & Johnson noted that current budget frameworks often fail to reflect the long-term and societal value of ATMPs, whilst a government official added that Belgium's public financing capacity is constrained. Industry representatives also pointed out that hospitals lack dedicated funding for the complex medical acts required to administer ATMPs.

Policy recommendations

To safeguard Belgium's leadership in ATMPs, collaboration across silos is essential to attract investments, simplify regulations, and ensure timely patient access. ***[Supply chain]*** Johnson & Johnson advocated for streamlining permitting and regulatory procedures (particularly around GMO authorizations and patient material imports), maintaining a competitive investment climate and modernizing educational curricula to meet the evolving needs of the cell and gene therapy sector. Industry stakeholders urged better alignment between industrial and healthcare policies to support high-value R&D and manufacturing, whilst ensuring stable energy infrastructure. ***[Regulatory requirements]*** Clinical trial agility should be restored by harmonizing approval processes & contract templates, according to Johnson & Johnson. FAMHP[2]'s ATMP Spearhead Initiative was supported by both government officials and Johnson & Johnson. Academia advocated for clarifying and improving the utilization of hospital exemption procedures, and recommended trusted data-sharing frameworks to unlock real-world evidence. ***[Accessibility]*** Johnson & Johnson advocated for reflecting the long-term and societal value of ATMPs in reimbursement evaluations, with budget impact assessments extending beyond the current three-year horizon. Industry called for the establishment of dedicated funding mechanisms for hospitals to support the administration of ATMPs. Government officials recommended enhancing cross-border collaboration and strategic horizon scanning to anticipate the growing pipeline of ATMPs and ensure sustainable financing through a multiannual pharmaceutical framework.

[1] Genetically modified organism
[2] Federal Agency for Medicines and Health Products: https://www.famhp.be/en

Foreword by J&J's Managing Director for Belgium and Luxembourg

Roxana Botea:

"Belgium stands at a pivotal moment in its journey to lead Europe's advanced therapy medicinal products (ATMPs) landscape. With a world-class life sciences ecosystem, a highly skilled workforce, and a legacy of public-private collaboration, our country has all the ingredients to become a true powerhouse in cell and gene therapy. Yet, we must acknowledge the growing urgency: international competition is intensifying, and significant challenges—ranging from complex regulatory pathways to talent pipeline and budgetary constraints—are testing our ability to remain at the forefront.

At J&J, we believe that ATMPs are not just scientific breakthroughs; they can be lifelines for patients with few or no other options. Our recent policy event brought together leading voices from across the ecosystem to confront the barriers that stand in the way of delivering these therapies "from plant to patient." The message was clear: Belgium's potential is immense, but realising it requires strategic vision and bold, coordinated action.

This white paper captures the insights and policy recommendations that emerged from our dialogue during the ATMP policy event in April 2025. We must act now to streamline regulations, unlock the potential of health data, and ensure that our reimbursement systems reflect the long-term value of innovation. The opportunity is there, but will only crystallize if we act with purpose, united by the same ambition – to make Belgium the undisputed leader in ATMP innovation, manufacturing, supply, and access.

I warmly invite all stakeholders to continue this dialogue and explore the recommendations presented throughout this paper as a shared foundation for action."

Why a dialogue on the potential of ATMPs in Belgium is needed

ATMPs are medicines based on genes, tissues or cells. They are broadly recognized to revolutionize the treatment of patients that often have no or limited effective therapeutic options. ATMPs include innovative treatments like CAR-T cell therapies, that modify a patient's own T-cells to target and destroy malignant cells, such as cancer cells. This therapy transforms the classic therapeutic administration into a complex multistep process, involving the collection of T-cells from the patient, that are transported to a production facility where they are genetically modified to include chimeric antigen receptors (CARs), after which they are returned to the patient. These therapies aim for a "one-and-done" effect, providing long-lasting results with a single treatment.

For this highly complex CAR-T cell therapy process, Belgium has a favorable ecosystem in place, **with 10% of European advanced therapy companies having Head Quarters in Belgium** and holds a strong footprint, with R&D investments quintupling over the past 25 years[3,4]. Around 2,600 clinical trials for ATMPs are underway globally, including 476 in the European Union.[5]

Significant challenges, however, are increasingly threatening Belgium's leading position in innovation, production, and patient access to ATMPs. Patient access to these innovative therapies remains challenging. According to an analysis between 2009 and 2024, 27 ATMPs received market approval in the EU. Of those, seven had been withdrawn from the European market[6] and at the time of the finalization of this white paper (October 2025) nine of those were commercially available and reimbursed for Belgian patients[7,8].
R&D investments in ATMPs specifically have declined in recent years in Europe, representing only 10% of global investments in this field[4].
For over 10 years, Belgium has been the country with the second highest number of clinical trials per capita. However, recent figures now show a declining trend in attracting trials to Belgium due to global competition[9,10].

To foster an **open dialogue on overcoming the silos between investments in supply & manufacturing, regulatory challenges, and access pathways**, J&J brought together key stakeholders (with representatives from the industry, academia, government and politicians) at the CAR-T production facility in the Tech Lane Science Park in Ghent on April 28, 2025 to define the journey and future of ATMPs "from plant to patient" in Belgium.

The J&J ATMP Policy Event underscored the **importance of moving beyond silo-thinking in strengthening supply chains, streamlining regulatory pathways, and improving patient access including sufficient financing in the ecosystem** to unlock the full opportunities of ATMPs for patients in Belgium and the broader life sciences sector. The panel discussions revealed a shared commitment among stakeholders at various governance levels to strengthen and sustain this ecosystem. Building on these insights, and drawing from its longstanding expertise in delivering innovative treatments to patients, J&J shares the key insights from the event followed by their own reflections and policy recommendations.

[3] https://pharma.be/sites/default/files/2024-12/report-to-society-2024_nl_0.pdf
[4] Deloitte: Realising the potential of Belgium's exceptional advanced therapy ecosystem (2024). Available https://www.deloitte.com/content/dam/assets-zone2/be/en/docs/services/consulting/2024/be-advanced-therapies.pdf
[5] Pharma.be: ATMPs. Available https://pharma.be/nl/atmps
[6] https://www.kce.fgov.be/sites/default/files/2025-01/KCE_396_Development_ATMPS_Belgium_Report.pdf
[7] https://www.riziv.fgov.be/SiteCollectionDocuments/liste_specialites_chapter4part1_20251001.pdf
[8] https://www.riziv.fgov.be/SiteCollectionDocuments/liste_specialites_chapter4part2_20251001.pdf
[9] https://efpia.eu/media/3edpooqp/assessing-the-clinical-trial-ecosystem-in-europe.pdf
[10] https://pharma.be/sites/default/files/2025-01/belgium-as-a-clinical-trial-location-in-europe-report-2023-publication-website-vf-sent.pdf

Key reflections and policy asks from the J&J ATMP policy event

1. We need to strengthen Belgium's business case to invest in the ATMP supply chain

> *"What makes Belgium a global leader in life sciences highlights the integration of the entire value chain - from R&D and production to export. J&J's investment in the production site in Ghent is therefore of utmost importance" – quote from political stakeholder*

The first panel included industry & government representatives and was preceded by insights from a political stakeholder. All panelists agreed that Belgium has a strong life sciences ecosystem that is well-positioned to take a leading role in ATMPs. However, it faces intense international competition and structural challenges, mainly driven by complex regulatory burdens and slow and uncertain permitting procedures. Hence, we urgently need a more assertive industrial policy to safeguard Belgium's competitiveness.

- ***Belgium's thriving life sciences ecosystem is supported by strong public-private partnerships in research and innovation****, as highlighted by both government representatives and industry stakeholders.* The government, supported by Johnson & Johnson, emphasized Belgium's unique capability to efficiently deliver the "vein-to-vein" process due to a well-functioning infrastructure (including the strategic role of Brussels Airport as a global pharma hub). In combination with the highly skilled talent in cell and gene therapy, significant investments landed in Belgium, such as the CAR-T production facility of J&J in cooperation with Legend Biotech at the Tech Lane Science Park in Ghent and the CAR-T facilities in Beerse. Industry panelists pointed to Belgium's competitive investment climate, including fiscal measures that incentivize R&D and can be seen as key drivers of the country's appeal for attracting global investments.

- ***Industry representatives also pointed out the unique opportunity of the EU Biotech Act,*** aiming to bolster the European Union's biotechnology sector, showcasing a positive mindset shift to adopt more assertive industrial policies.

- ***However, panelists identified several structural challenges that could undermine Belgium's attractiveness for future investments in ATMP manufacturing.*** Complex regulatory procedures, particularly around operating licenses and the import of critical patient materials like blood samples, impose significant hurdles for companies such as J&J. In addition, industry argues that high labor expenses are not easing the competitive battle between other regions and that it is highly important to secure a stable energy grid guaranteeing 24/7 uninterrupted supply. Despite the current skilled workforce, the talent pipeline needs continuous attention for companies like J&J, to ensure that bachelor's programs are fully aligned with the evolving needs of the cell and gene therapy sector. The governmental stakeholder pointed out the importance of quick market access for new therapies in Belgium where R&D investments are also made.

- ***To secure Belgium's competitiveness, panelists from both industry and government called for more assertive policies that addresses structural challenges.*** Johnson & Johnson representatives emphasized the importance of preserving and adapting the current investment framework to remain internationally competitive in attracting high value R&D and manufacturing. Industry stakeholders advocated for aligning industrial and healthcare policies with the specific priorities of the life sciences ecosystem, highlighting the need to simplify import regulations for patient materials and modernize educational curricula to meet the evolving needs of the cell and gene therapy sector (as specifically noted by J&J), and accelerate market access procedures (supported by both industry and government representatives). Industry panelists also underscored the necessity of sustained investment in energy infrastructure to ensure a stable and reliable energy supply that can support large-scale manufacturing. Finally, they also urged the expansion of public-private partnerships, not only to support R&D, but also to de-risk the early production phase and foster lifelong learning initiatives.

Reflections from Johnson & Johnson on attracting ATMP investments to Belgium

1) We should prioritize fostering a strong and predictable investment climate including fiscal measures that incentivize R&D, reduce unnecessary time to operational launch due to gold plating regulations and implement balanced and flexible climate policies.
2) It is crucial to secure a competitiveness deal that takes into account biopharma and life science industry.
3) The investments made at manufacturing level and attracting clinical trials eventually need to benefit Belgian patients. We therefore also need a competitive environment for fast and sustainable access to innovation.
4) The EU Biotech Act presents a unique opportunity to improve coherence across different (non)legislative frameworks and to avoid duplication or inconsistencies. For example, it presents an opportunity to create a 'single market for clinical trials' with a centralized assessment to improve the regulatory predictability, reduce the regulatory burden and streamline the clinical trial process.

2. Enhancing the regulatory & clinical trial framework for ATMPs in Belgium

"We should maximize the efficiency of patient recruitment in Belgium by unlocking real-world data to truly serve clinicians, policymakers, and the pharmaceutical sector, in a way that fully respects GDPR. Nordic countries like Denmark show us what's possible with strong national registries and systematic patient follow-up." – quote from an academic stakeholder

In the second panel the regulatory bottlenecks, particularly those affecting clinical trials, were discussed by representatives from Johnson & Johnson, government and academic institutions and were reflected upon in a final keynote by a political stakeholder. All stakeholders agreed that Belgium has secured a leading position in clinical trials, citing various contributing factors. However, Johnson & Johnson raised concerns about Belgium's ability to remain competitive under the EU Clinical Trial Regulation (EU CTR). In a closing political speech, it was stressed that beyond economic benefits, clinical trials offer patients early access to innovative treatments, underscoring their broader societal value.

- ***Panelists highlighted several strengths that position Belgium as an attractive location for ATMP clinical trials.*** Academic speakers emphasized the availability of a highly skilled talent pool in cell and gene therapy research, and noted that Belgium's rich repositories of patient health data offer significant potential to generate real-world evidence, which could support patient identification and improve treatment outcomes. Johnson & Johnson and government stakeholders pointed to the existence of fast-track procedures for mono-national Phase I trials as a key enabler for early-stage clinical development. The government also underscored the importance of experienced regulatory authorities, such as the FAMHP, and recognized the ATMP Spearhead Initiative as a positive step toward reinforcing regulatory expertise and streamlining approval processes.

- ***However, Johnson & Johnson emphasized that the harmonization of approval timelines under the EU Clinical Trials Regulation (EU CTR) has weakened Belgium's former competitive edge in approval timelines.*** In addition, Belgium's smaller population size was noted as a structural challenge to its capacity for patient recruitment in clinical trials. J&J also mentioned ongoing regulatory complexities, particularly the complex and non-harmonized framework for genetically modified organisms (GMOs) as a persistent challenge. The academic speaker highlighted financial and regulatory challenges in the early clinical development under the hospital exemption pathway, lacking financial means for early development of academic ATMPs and in the reimbursement of ATMPs developed under hospital exemption. Furthermore, the academic expert emphasized that Belgium's rich health data repositories remain underutilized, largely due to the absence of mechanisms that enable access for relevant stakeholders, including industry partners.

- ***Johnson & Johnson called for targeted policy action to simplify and harmonize regulatory processes, particularly around GMO authorizations.*** To further enhance Belgium's clinical trial environment, the J&J representative also supported accelerating approval timelines and FAMHP's ATMP Spearhead Initiative as a means to strengthen regulatory expertise in ATMP and streamline procedures. In addition, the academic expert stressed the importance of unlocking Belgium's rich health data to generate real-world evidence, drawing inspiration from best practices in Nordic countries with national cancer registries and robust patient follow-up systems, while ensuring full compliance with GDPR. Finally, a government official highlighted the importance of sustained investment in multi-stakeholder platforms to foster collaboration and improve predictability in patient recruitment.

Reflections from Johnson & Johnson on fostering a stimulating regulatory environment for ATMPs

1) To keep our top position in attracting clinical trials, we should improve start-up timelines by avoiding duplicative approval processes and harmonizing contract templates. To reduce administrative burden, we should streamline existing regulatory processes and avoid duplication, especially for ATMPs with a GMO component.

2) Because of its smaller size, Belgium should adopt a way to optimally recruit the available patient pool, taking into account a shift towards more centralized treatments in larger expert centers, especially for highly innovative treatments such as ATMPs.

3) Belgium could also pioneer at the level of attracting clinical trials that cover future needs and innovative technologies and processes.

4) Unlocking health data requires a mindset shift and should be built on trust and transparency to citizens and patients. Johnson & Johnson is contributing by setting up a collaborative CAR-T data network to obtain data registration and administrative simplification to save time and improve patient follow-up, that can be integrated into registers at local level and European level and that can serve as a blueprint for future data networks.

5) While we acknowledge the importance of the hospital exemption pathway as a complementary route to EMA/EC centrally approved ATMPs to address unmet medical needs, it is essential that policy solutions are developed collaboratively among all stakeholders to foster a level playing field. Therefore, J&J supports efforts to clarify regulatory requirements by the Belgian example tailoring hospital exemption use to cases where there is no alternative approved medicines product, clinical trial or compassionate use program available to patients. This approach will help unlock the full potential of advanced therapies for Belgian patients, while maintaining high standards for safety, quality, and patient access, regardless of where or by whom they are produced.

3. Facilitating access(ability) to ATMPs for patients in Belgium

"Belgium has proven it can build a successful end-to-end value chain - from R&D to manufacturing and patient access. These cutting-edge therapies offer new hope to patients and their families, moreover they also benefit society by helping patients lead active, productive and longer lives. For me, this is what competitiveness truly means." – quote from Johnson & Johnson

While Belgium's life sciences ecosystem is increasingly positioned as a hub for R&D and supply chain activities in the field of ATMPs, this ambition is accompanied by notable challenges in ensuring patient access, as highlighted in a third panel by Johnson & Johnson and another industry stakeholder. Both highlighted that Belgium's ambition to be a top European player in ATMPs should not only apply to innovation and manufacturing but should also extend to accessibility for patients. To do so, both the J&J and industry representatives underlined the necessity of evaluating the long-term value of ATMPs and considering their implications for clinical practice, particularly in a constrained budget environment that fails to consider longer-term cost reductions in different domains. The government stressed the importance of strategic horizon scanning and the increasing importance of international collaboration to address long-term effectiveness.

- ***Belgium consistently ranks among Europe's innovation leaders, a point emphasized by an industry representative who credited this position to the country's collaborative network of universities, healthcare institutions, and pharmaceutical companies.*** A Johnson & Johnson representative highlighted Belgium's structured pricing and reimbursement procedures, which include clinical assessments followed by health economic evaluations and the possibility managed entry agreements, further strengthening Belgium's ability to deliver new therapies to patients while effectively managing the costs. Additionally, the J&J representative noted that hosting companies capable of integrating the full end-to-end value chain, from R&D to patient access, further positions Belgium as a top European hub for ATMP innovation and delivery.

- ***Despite Belgium's thriving life sciences ecosystem, the industry, supported by Johnson & Johnson, pointed out that the country continues to face significant barriers to timely and equitable patient access to ATMPs***. Johnson & Johnson thereby emphasized that the long-term and societal value of ATMPs is often overlooked in current reimbursement evaluations, calling for a fundamental rethinking of how these therapies are assessed. A government official emphasized the broader budgetary reality, which is shaped by political willingness and constrained by Belgium's public financing capacity. An industry stakeholder further noted that hospitals administering ATMPs face substantial financial and operational burdens due to insufficient funding, highlighting that several medical acts involved in ATMP administration are not reimbursed under the current nomenclature. In addition, the industry stakeholder stressed that limited data sharing among treatment and referral centers hampers coordinated patient follow-up and effective outcome tracking.

- ***Panelists from the industry urged Belgian policymakers to adopt an integrated strategy that aligns with the ambitions of the life sciences ecosystem, not only in R&D and manufacturing, but also in ensuring patient access.*** A Johnson & Johnson representative emphasized the importance of reflecting the long-term and societal value of ATMPs in reimbursement evaluations, advocating for a budget impact assessment that extends beyond the current three-year horizon to better manage upfront costs and alleviate financial pressures. To support the delivery of ATMPs, the industry representative also called for dedicated funding mechanisms to help hospitals administer these complex therapies. A government official highlighted the essential role of cross-border collaboration on health technology assessment (HTA) and horizon scanning to anticipate the growing pipeline of ATMPs. Finally, in a closing keynote speech, a policymaker stressed the need for a multiannual pharmaceutical framework at the federal level to ensure sustainable financing and proactively address Belgium's budgetary challenges.

Reflections from Johnson & Johnson on improving access to ATMPs

1) To keep securing investments in and by the Belgian biopharmaceutical industry, we need a competitive market that attracts, values & rewards innovation. To welcome new innovative therapies to Belgian patients, the market needs to prepare, foresee sufficient budget and allow for early reimbursement possibilities.
2) To secure a more predictable reimbursement outcome, different steps in the reimbursement process should be streamlined and the full potential of an ATMP should be reflected, including its societal and long-term benefits over a timeframe longer than three years.
3) There is no innovation without a robust intellectual property framework. We therefore need a stimulating IP framework that is safeguarded for innovation.
4) ATMPs are complex and require multiple medical acts (e.g. leukapheresis) which should be financially viable for a hospital. Additional costs related to the implementation of ATMP's in clinical practice should be reimbursed, for example through specific nomenclature and funding for data collection.
5) Enhancing patient outcomes in real-world clinical practice requires a comprehensive data infrastructure and well-defined policies to ensure consistent follow-up and facilitate improved referral between hospitals.

Conclusion

Belgium stands at a pivotal moment in its journey to lead Europe's advanced therapy medicinal product (ATMP) landscape. While the country benefits from a world-class life sciences ecosystem, significant challenges threaten its ability to remain competitive. Addressing these challenges with targeted, sector-specific policies is essential to unlock the full potential of ATMPs—from research and manufacturing to patient access. Below you can find the conclusions of each panel concerning the key challenges & policy recommendations, complemented by the J&J reflections.

1. Structural and industrial barriers

Key challenges raised by the panel:

- **Complex and slow licensing procedures** delay ATMP manufacturing and risk discouraging future investment in Belgium. Rapid market access for new therapies is essential, especially where R&D investments have been made (*industry, government and Johnson & Johnson)*.
- **High labor costs** reduce Belgium's competitiveness compared to other regions, whilst ensuring stable energy supply is a growing concern *(industry representative)*.
- **Attention needed to align educational programs and sector needs** to ensure future talent pipeline for cell and gene therapy (*Johnson & Johnson)*.

Policy recommendations from the panel:

- **Accelerate operational launch** *(Johnson & Johnson)*: by simplifying regulations, such as for import of patient materials.
- **Attract and support large-scale manufacturing to Belgium** *(industry and Johnson & Johnson)*: by keeping a competitive investment climate and ensuring stable energy infrastructure.
- **Align industrial and healthcare policies to support high-value R&D and manufacturing** *(industry)*: by better aligning to ensure that the specific priorities of the life sciences ecosystem are addressed.
- **Accelerate market access of ATMPs** *(industry and government representatives)*.
- **Modernize educational curricula** *(industry and Johnson & Johnson)*: align university and college programs with the evolving needs of the cell and gene therapy sector.

Johnson & Johnson's Recommendations Following the ATMP Policy Event:

- **Preserve a competitive investment climate and address gold-plating regulations** to speed up operational launch for high-value R&D and manufacturing, while ensuring climate policies remain balanced and flexible.
- **Implement a competitiveness deal** that takes into account biopharma and life sciences industry.
- **Ensure that investments in manufacturing and clinical trials benefit Belgian patients** by fostering a competitive environment for access to innovation.
- **Use the opportunity of the EU Biotech Act to simplify regulation** and strengthen Member State attractiveness, by creating a **single market for clinical trials with a centralized assessment**.

2. Regulatory bottlenecks

Key challenges raised by the panel:

- **Reduced agility under EU CTR**, a lack of streamlined approval processes and no harmonized contract templates delay clinical trial start-up and reduces attractiveness for clinical trials due to global competition *(Johnson & Johnson)*.
- **Fragmented and unclear frameworks** around GMO create regulatory uncertainty *(Johnson & Johnson)*.
- **Financial and regulatory challenges** hamper the early clinical development under the hospital exemption pathway *(academia)*.
- **Limited access to health data** due to unclear sharing frameworks hampers efficient patient recruitment and real-world evidence generation *(academia)*.

Policy recommendations from the panel:

- **Harmonize and simplify regulatory procedures** *(Johnson & Johnson)*: avoid duplication, improve trial start-up timelines and streamline processes.
- **Support the FAMHP's ATMP Spearhead Initiative** *(government official and Johnson & Johnson)*: build regulatory expertise and streamline approvals.
- **Improve the utilization of hospital exemption** mechanisms in Belgium *(academia)*: clarification of the regulatory pathway is needed to ease using the existing hospital exemption pathway.
- **Unlock health data through trusted frameworks** *(academia)*: establish transparent, GDPR-compliant data-sharing mechanisms to enable real-world evidence that could support patient identification and improve treatment outcomes.
- **Foster collaboration through multi-stakeholder platforms** *(government official).*

Johnson & Johnson's Recommendations Following the ATMP Policy Event:

- **Improve start-up timelines** by avoiding duplicative approval processes, harmonizing contract templates and streamlining regulatory processes, especially for ATMPs with GMO component.
- **Adopt optimal patient recruitment strategies** for Belgium's smaller population, taking into account the shift towards centralized treatments in expert centers.
- **Belgium to pioneer in attracting clinical trials for future needs and innovative technologies** by establishing trusted, collaborative health data networks, built on transparency and citizen trust.
- Regulatory requirements should be clarified by the Belgian example tailoring hospital exemption use to cases where there is no alternative approved medicines product, clinical trial or compassionate use program available to patients.

3. Access and reimbursement constraints

Key challenges raised by the panel:

- **Significant barriers to timely and equitable patient access to ATMPs remain** *(industry and Johnson & Johnson)*.
- **Current budget frameworks do not reflect the long-term and societal value of ATMPs**, focusing only on short-term cost impact *(Johnson & Johnson)*. On this short term, Belgium's financing capacity is constrained *(government official)*.
- **Hospitals lack dedicated funding for the medical acts and interventions to administer ATMPs**, creating operational and financial strain *(industry)*.
- **Fragmented follow-up systems and poor data integration** hinder outcome tracking and real-world evidence generation *(industry)*.

Policy recommendations from the panel:

- **Adopt an integrated strategy for patient access** *(industry and Johnson & Johnson)*: align ambitions in R&D, manufacturing, and access, ensuring the ATMP investments ultimately reach Belgian patients.
- **Reflect the long-term and societal value of ATMPs in reimbursement evaluations** *(Johnson & Johnson)*: with a budget impact assessment that extends beyond the current three-year horizon.
- **Establish dedicated funding mechanisms for hospitals** *(industry)*: support the delivery of ATMPs by covering the costs of complex medical acts.
- **Enhance cross-border collaboration and strategic horizon scanning** *(government officials)*: anticipate the growing pipeline of ATMPs and ensure sustainable financing through a multiannual pharmaceutical framework.

Johnson & Johnson's recommendations following the ATMP policy event:

- **Foster a competitive market that attracts, values, and rewards innovation**, ensuring sufficient budget and early reimbursement possibilities for new therapies.
- **Streamline reimbursement processes** and reflect the full potential of ATMPs, including societal and long-term benefits over a timeframe longer than three years.
- **Safeguard a robust intellectual property framework** to stimulate innovation and ensure financial viability for hospitals administering ATMPs, supported by comprehensive data infrastructure and policies for consistent patient follow-up.

Belgium has the ingredients to become a true powerhouse in ATMP innovation. But to realize this potential, bold and coordinated action is needed across industrial, regulatory, and healthcare domains. By implementing these targeted policy measures, Belgium can secure its position as a leading European hub for advanced therapies and continue delivering transformative treatments from plant to patient.

About Johnson & Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity

Belgium plays a strategic role in Johnson & Johnson's global CAR-T operations, covering the end-to-end process - from the Beerse campus, where T-cell cryopreservation takes place, to the CAR-T production facility in Ghent, where lentiviral vector is added to the T-cells. The site at the Tech Lane Science Park in Ghent hosts the first European CAR-T production facility, in cooperation with Legend Biotech.