Poster #6787

Challenges and Opportunities in the Dutch Lock Procedure: Improving Access and Reimbursement Timelines for Cell and Gene Therapies in the Netherlands

Donders J.[1,2], Borghouts- de Ruijter A.[1]

1 Gilead Sciences, Amsterdam the Netherlands; 2 MSc, Master program in Oncology, Vrije Universiteit Amsterdam, Amsterdam the Netherlands

BACKGROUND

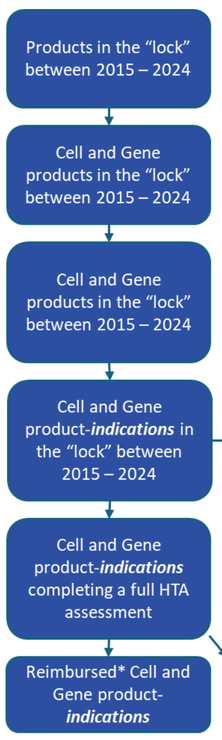
Despite numerous European Medicines Agency (EMA) approvals, patient access to cell and gene therapies across Europe remains delayed - averaging 578 days[1] per the EFPIA W.A.I.T. indicator. In the Netherlands, "lock procedure" treatments take around 600 days[2] to become available.

OBJECTIVES

To compare the number of reimbursed Cell and Gene product-indications in the Netherlands versus select European countries, analyzed reimbursement timelines, and identified key Health Technology Assessment (HTA) challenges in the Netherlands.

METHODS

PHASE 1
Focus on the Netherlands (NL)



*Data cut-off 1 May 2025

Figure 1 Overview of Cell and Gene therapies in the Dutch "lock procedure" (2015–2024). A total of 91 products entered the lock procedure during this period. Of these, 18 were identified as cell and gene product-indications.

Total number of indications reimbursed, reimbursement timelines, key challenges in HTA procedures. Cell and gene therapies entering the lock between January 1, 2015, and December 31, 2024, were identified. Data were sourced from EMA and Ministry of Health, Welfare, and Sport (VWS) websites; HTA challenges from publicly available assessment reports.

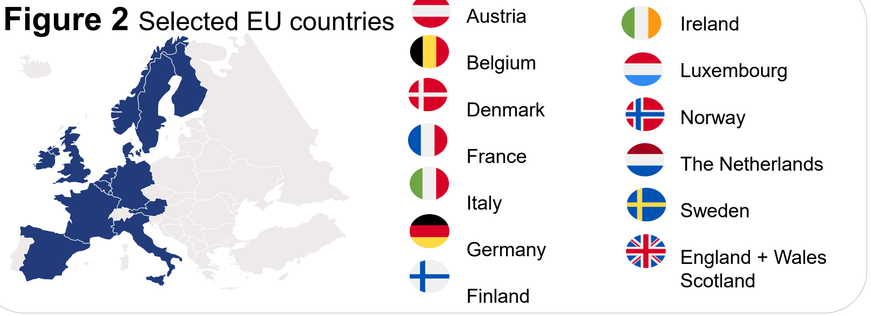
Reimbursed Cell and Gene product-indications: considered for calculating reimbursement timelines: time between EC (European Commission) decision and local reimbursement

Reimbursed Cell and Gene product-indications completing a full HTA assessment: considered for in-depth analysis on HTA challenges and trends: pharmacotherapy, pharmacoeconomy and budget impact

PHASE 2 Focus NL vs EU

Total number of indications reimbursed in selected EU countries.** Data was collected through market access expert input across Europe. All data is publicly available.

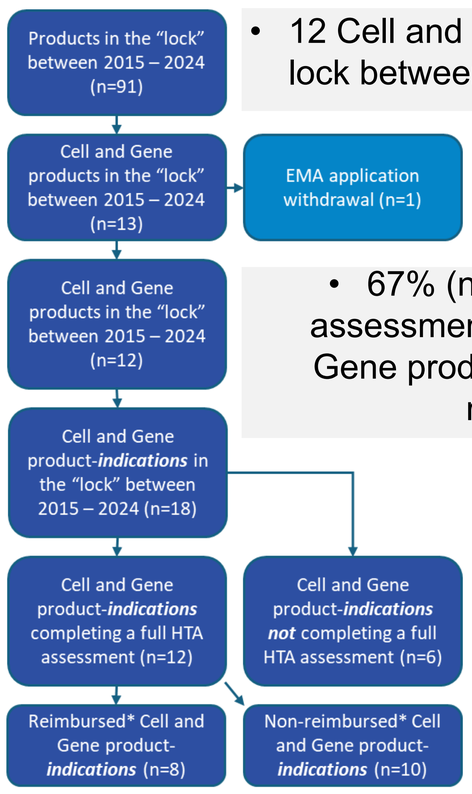
Figure 2 Selected EU countries



**UN geographic regions Western Europe and Northern Europe, including EU4, excluding countries with <5 Mio inhabitants, and countries corresponding to the Beneluxai initiative (Belgium, Netherlands, Luxembourg , Austria, Ireland).

RESULTS

PHASE 1



*Data cut-off 1 May 2025

- 12 Cell and Gene products covering 18 product-indications entered the lock between January 2015 and December 2024.
- 67% (n=12) completed a full HTA assessment and 44% of the Cell and Gene product-indications (n=8) were reimbursed at data cut-off*
- 46% (6/13) for Cell products
- 40% (2/5) for Gene products

Figure 3 Product-indication selection process

	Product-indication	Reimbursement status
Cell Therapy	1	
	2	
	3	
	4	
	5	
	6	
	7	
	8	
	9	
	10	
	11	
	12	
	13	
Gene Therapy	1	
	2	
	3	
	4	
	5	

Figure 4 Product-indication reimbursed*

Green = reimbursed; Red = not reimbursed

- The average time between EC-decision and local reimbursement was 781 (131 – 1.376) days for Cell and Gene therapies combined (n=8).

Pharmaco*therapeutic* challenges

100% of the time mentioned as key challenge (n=12)

- Single-arm trial design
- Immature follow-up data

Pharmaco*economic* challenges

50% of the time mentioned as key challenge (n=6)

- Driven by pharmacotherapeutic uncertainties

Budgetary challenges

50% of the time mentioned as key challenge (n=6)

- Primarily driven by uncertain number of patients (in specific Lines of Treatment)

PHASE 2

Cell therapies

Product-indication	Austria	Germany	Italy	France	Luxembourg	England + Wales*	Finland	Spain	Sweden	Scotland*	Denmark	Netherlands	Belgium	Norway	Ireland*
1															
2															
3															
4															
5															
6															
7															
8															
9															
10															
11															
12															
13															
Total Cell	13	12	10	10	9	6	9	8	7	7	6	6	6	5	3
	100%	92%	77%	77%	69%	46%	60%	62%	54%	54%	46%	46%	46%	38%	23%

Gene therapies

Product-indication	Austria	Germany	Italy	France	Luxembourg	Finland	Spain	Sweden	Scotland*	Denmark	Netherlands	Belgium	Norway	Ireland*
1														
2														
3														
4														
5														
Total Gene	3	4	2	1	2	4	1	2	3	3	4	2	1	2	1
	60%	80%	40%	20%	40%	80%	20%	40%	60%	60%	80%	40%	20%	40%	20%
TOTALS	**16**	**16**	**12**	**11**	**11**	**11**	**10**	**10**	**10**	**10**	**10**	**8**	**7**	**7**	**4**
	89%	**89%**	**67%**	**61%**	**61%**	**61%**	**56%**	**56%**	**56%**	**56%**	**56%**	**44%**	**39%**	**39%**	**22%**

Figure 5 Overview reimbursement status on 1 May 2025.

Green = available to patients;

Red = not available for patients.

*Not validated yet by country-expert.

**In various countries Carvykti is available for MM 2L+.

- Average uptake and availability of Cell and Gene product-indications is highest in Austria and Germany and lowest in the Netherlands, Belgium, Norway and Ireland

CONCLUSIONS

Cell and gene therapy availability varies widely across the EU, with the Netherlands among the lowest. The requirement for long-term, published data delays submissions and patient access. While price reductions are often seen as a solution to accelerate access, this study shows that in the Netherlands, therapeutic uncertainties are central to HTA evaluations, driving downstream economic concerns, ultimately resulting in conservative price recommendations.

REFERENCES

1. Max newton, kelsey stoddart, marco travaglio & per troein. *EFPIA patients W.A.I.T. Indicator 2024 survey* . https://efpia.Eu/media/oeganukm/efpia-patients-wait-indicator-2024-final-110425.Pdf (2025).
2. De medicijnsluis: hoe nu verder? - Vereniging innovatieve geneesmiddelen. Https://www.Verenigginnovatievegeneesmiddelen.Nl/kennisbank/de-medicijnsluis-hoe-nu-verder/.

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