Pricing analysis of Value-Added Medicines in Europe: a call for recognition of patient-centric innovation

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INTRODUCTION

Reformulations and fixed-dose combination (FDC) value-Added Medicines (VAMs) may offer patient-centric innovation by improving outcomes, convenience or safety. Yet, their pricing and reimbursement (P&R) landscape in Europe remains fragmented and unpredictable. We set out to seek clarity on questions like:

- Are there any VAMs that achieve premium prices vs reference medicines? If so, how do they do it?
- What evidence and value drivers of VAMs matter most to European payers?
- What actionable steps can improve patient access to VAMs?

OBJECTIVE

Evaluate the P&R landscape for VAMs across key European countries and to identify HTA and pricing trends and to gather insights on payer perspectives on VAMs and areas of improvement.

METHODOLOGY

IQVIA and Viatris conducted a landscape review of 10 VAM analogues**, focusing on reformulations and FDCs, across EU4, UK and Sweden. HTA outcomes, pricing trends, and value drivers were identified for these ten VAM analogues.

RESULTS

Select reformulated VAMs achieved significant price premiums (up to +1,000%) vs reference medicines, even with modest HTA outcomes or limited HTA participation. Conversely, most FDCs launch at a discount versus loose combinations and rarely achieve parity, even where robust clinical benefits are demonstrated.

Table 1. HTA & pricing outcomes of VAM analogues at launch*

[C1: HTA outcomes] [C2: % price ↑ or ↓; daily treatment cost per patient vs reference medicine in EUR]

Pricing vs reference medicine: Premium | Parity | Discount | Not available

			EU	DE		FR		IT		ES		UK		SE	
	Okedi	Feb 2022		**+1532%;** €13.32 vs €0.82				**+2282%;** €9.47 vs €0.40		**+2888%;** €7.87 vs €0.26		**+754%;** €8.09 vs €0.95			
	Baqsimi**	Dec 2019		**+359%;** €79.00 vs €17.20		**+481%;** €77.50 vs €13.30		**+487%;** €85.40 vs €14.50		**+395%;** €68.00 vs €13.70				€87.50ϕ	
	Buvidal***	Nov 2018		**+20%;** €9.30 vs €7.70		**+88%;** €11.90 vs €6.30				€9.10ϕ		**+61%;** €8.13 vs €3.19		**+153%;** €12.20 vs €4.80	
	Evorel	DE: Jun 2008 UK: Apr 2009		**+30%;** €0.34 vs €0.26								**230%;** €0.45 vs €0.13			
	Catiolanze***	Nov 2023		**64%;** €16.30 vs €9.97						**+220%;** €9.33 vs €2.92				**+209%;** €9.99 vs €3.23	
	Monoprost***	Jan 2017		**23%;** €12.30 vs €10.00		**12%;** €3.40 vs €3.04		**-70%;** €2.52 vs €8.32		**0%;** €4.86 vs €4.86		**-59%;** €3.80 vs €9.92		**+209%;** €9.99 vs €3.23	
	Nustendi	Mar 2020		**-43%;** €1.87 vs €3.29				**-16%;** €2.60 vs €3.10		**-25%;** €2.12 vs €2.83		**-34%;** €2.02 vs €3.06			
	Steglujan	Mar 2018		**-2%;** €1.81 vs €1.84				**+0.4%;** €2.44 vs €2.43						**0%;** €1.99 vs €1.98	
	Suliqua	Jan 2017		**-49%;** €1.78 vs €3.49				**-26%;** €2.13 vs €2.88				**-46%;** €1.53 vs €2.80		**+3%;** €1.68 vs €1.63	
	Twicor	Oct 2018				**-51%;** €0.60 vs €1.22		**-25%;** €2.12 vs €2.83		**-21%;** €0.81 vs €1.03					
	Zenon	Mar 2019		**-72%;** €0.60 vs €2.14		**-51%;** €0.60 vs €1.22				**-14%;** €0.81 vs €0.95					

* Prices reported here are ex-Mnf prices and net prices in markets may vary especially at the KK-level in Germany where tendering at the retail-level is likely. Price premium or discount is considered if percent price difference is >+15% or <-15% respectively. ** Price reported as cost of treatment per event per patient. *** Price reported as cost per month per patient. ϕ The reference medicine is not available in the market and therefore no price percent difference can be calculated in this instance. C1= column 1; C2= column 2

HTA outcome (first column for each country): Positive | Neutral | Negative | Not assessed | Not launched

Key: New RoA (reformulation) | New formulation (reformulation) | FDC

Premium pricing for VAMs vs their reference medicine is driven by:

- Narrower target populations (e.g., Okedi in a sub-population of schizophrenia)
- Clinical or safety benefits (e.g., Buvidal's compliance-driven improved efficacy)
- Patient-reported outcomes (PROs) & QoL improvements (e.g., Baqsimi's nasal spray reducing caregiver burden)
- Cost-offsets (e.g., Monoprost's room temperature storage in reducing supply chain & storage costs)

Evidence requirements for achieving premium pricing for VAMs are established and require robust, statistically significant evidence of clinical, patient, or economic benefit in a targeted population, while discounted or parity pricing can be supported by minimal studies.

Table 2. Value drivers of premium pricing for select VAM analogues vs reference medicine

	New RoA				New formulation		Fixed dose combinations (FDCs)			
	Okedi	**Baqsimi**	**Buvidal**	**Evorel**	**Catiolanze**	**Monoprost**	**Nustendi**	**Steglujan**	**Suliqua**	**Twicor/Zenon**
Therapeutic area-related										
Unmet medical need										
Product positioning*										
Narrower target population vs reference medicine	[Mnf]	[Payer]	[Payer]			[Payer]				
High price of ACTs in the target population										
Clinical evidence & patient-experience										
Efficacy and safety benefit										
PROs and QoL										
Adherence and/or convenience**										
Caregiver burden										
Health-economic evidence										
Healthcare resource utilisation										
Cost-offsets e.g., increase in shelf-life, storage benefit										

* Product positioning can be defined by the manufacturer [Mnf] who incorporate a sub-population in their label or by the payer who impose population restrictions.
** The attribute is only considered a driver of price premium if the benefit is linked to improvement in clinical outcomes.

Premium pricing: Driver | Not considered/ not a factor

CONCLUSIONS & NEXT STEPS

Our research highlights encouraging examples where the value of VAMs has been successfully assessed and recognized by payers, demonstrating that rewarding meaningful innovation is possible. However, the absence of clear frameworks and the inconsistency of evaluation standards across countries make it difficult for manufacturers to anticipate how their innovations will be valued. Although manufacturers are expected to provide robust, payer-relevant evidence, the unpredictability of how this evidence is interpreted often results in uneven recognition of value. Consequently, many VAMs — particularly FDCs — continue to be priced at a discount or at best parity to their reference medicines, even when they offer meaningful improvements in administration or adherence. While the evidence requirements for achieving premium pricing are becoming clearer — typically requiring statistically significant clinical, patient, or economic benefit linked to improved outcomes — greater predictability and structure in how such evidence is assessed are needed. The level of investment required to generate this data is often not proportionate to the potential reward, and the fragmented nature of HTA and pricing & reimbursement frameworks for VAMs across European countries continues to hinder consistency in how innovation is valued and subsequent patient access.

To unlock the full potential of VAMs, we call on European payers and HTA bodies to establish transparent, consistent evaluation criteria that recognise and reward meaningful patient-centric innovation. We also invite all payer stakeholders to join an open dialogue and guide manufacturers in generating the evidence for VAMs that truly matters for patients and payers alike.

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**The selection of VAM analogues was not representative of the broader landscape; the sample was cherry-picked, focusing primarily on positive cases where premium pricing was achieved. This may introduce bias and limit generalisability of the findings.
Abbreviations: ACTs, appropriate comparator therapies; **HTA,** health technology assessment; **QoL,** quality of life; **RoA**, route of administration.
Sources: Publicly available HTA reports, IQVIA MIDAS, IQVIA Pricing Insights

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