

IMS Health & Quintiles are now



Why are Value Added Medicines so Important?

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Medicines for Europe, Brussels

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Strong forces driving changes in Healthcare



Ageing population



Rising prevalence of chronic diseases



Adherence/Compliance



Rising cost of care and increasing scrutiny around value



Increasing connectivity and Healthcare Consumerism



Patient Centricity

Significant unmet needs still exist in primary care

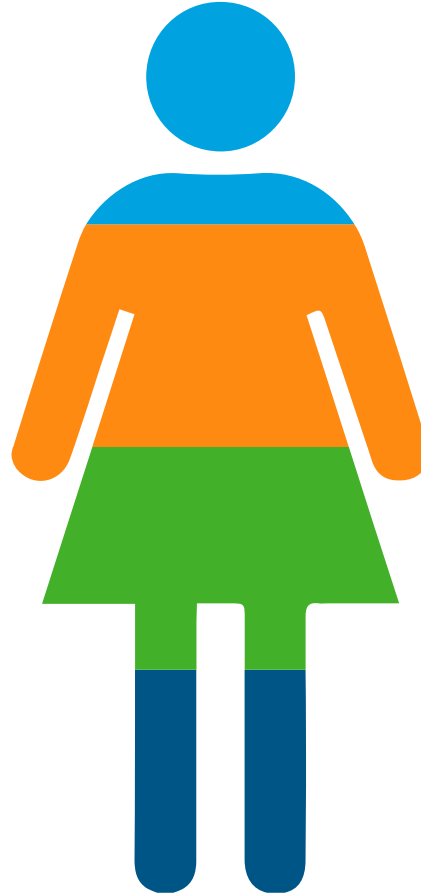
Ultimately, all chronic conditions are waiting for a curative or prophylactic treatment option

Efficacy

- Lack of effective treatment options, eg NASH, AD, migraine, obesity
- Uncontrolled patient sub-segments, eg high-risk dyslipidemia, severe asthma, T-R depression

Tolerability

- GI side effects
- Drug-drug interactions, especially in co-morbid patients



Safety

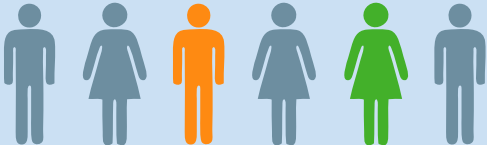
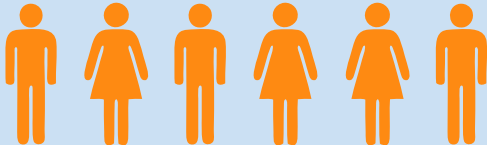
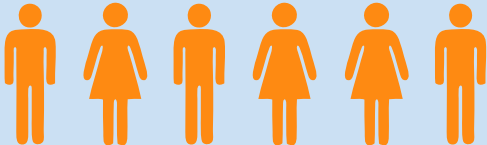
- Long-term safety, eg renal, liver, CV, CNS risks
- Narrow therapeutic windows; ongoing monitoring requirements

Convenience

- Complex regimens, high pill burden, food requirements
- Formulation: injectables, eg GLP-1, insulins; pill size; dosing frequency

The opportunity for primary care innovators presents itself in three segments

Existing treatment landscape

	Broadly satisfactory <i>Available options, generally effective across patient population</i>	Unsatisfactory <i>Available options, but limited overall effectiveness or high treatment burden</i>	None <i>No disease-specific/-modifying treatment options available</i>
Unmet need	 <p>Generally well-served population; unmet need in specific sub-segments (eg severe, high risk, non-responders)</p>	 <p>Broad, underserved patient population across a TA</p>	 <p>Broad, underserved patient population across a TA</p>
Examples	Dyslipidaemia, asthma, depression, diabetes, osteoporosis, pain	Alzheimer's, obesity, migraine, anti-coagulants	NASH, NAFLD
Opportunity for innovators	Address specific sub-segments, eg <ul style="list-style-type: none"> Highly targeted 1st line treatment Entering market in later line 	Revive a 'stalled market'	Create a new market

Value Added Medicines

However, primary care innovators face a number of barriers



Regulators

- Evidence requirements don't recognize the nature of primary care innovation
- Adaptive pathways typically focussed on specialty care



Payers

- 'Good enough' mindset
- Price expectations anchored on mature, often generic, comparators
- Push for **narrow target patient populations**
- Pricing & access approaches **don't consider adequate ROI**



Providers

- Care settings not joined up
- Challenge to **identify eligible patients** in clinical practice
- Unfamiliar with novel mode of administration (eg biologics)
- **Capacity constraints**, eg administration (if IV, inject.)
- Dis-incentives, eg procedures not covered in office setting



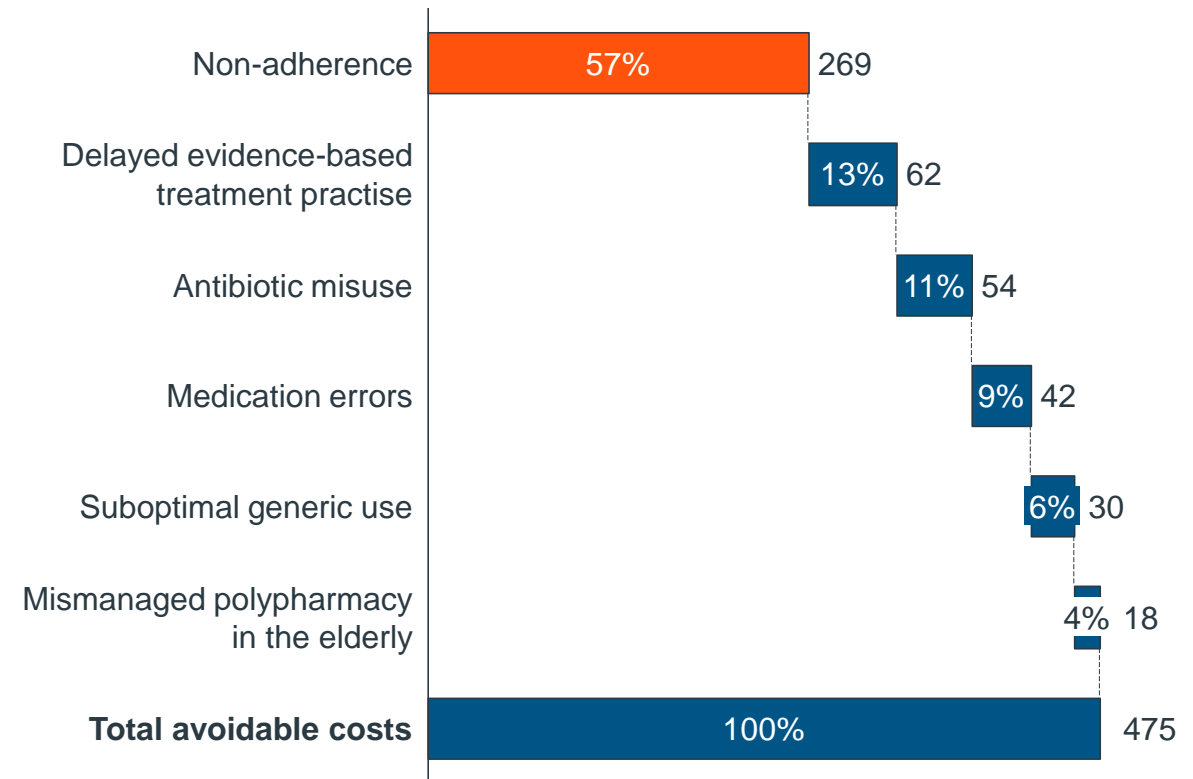
Patients

- Lack of **disease awareness**, esp. if it previously lacked treatment options
- Lack of awareness of novel treatment options
- **Struggle to navigate** fragmented patient journey
- **Resistance** to non-oral route of administration

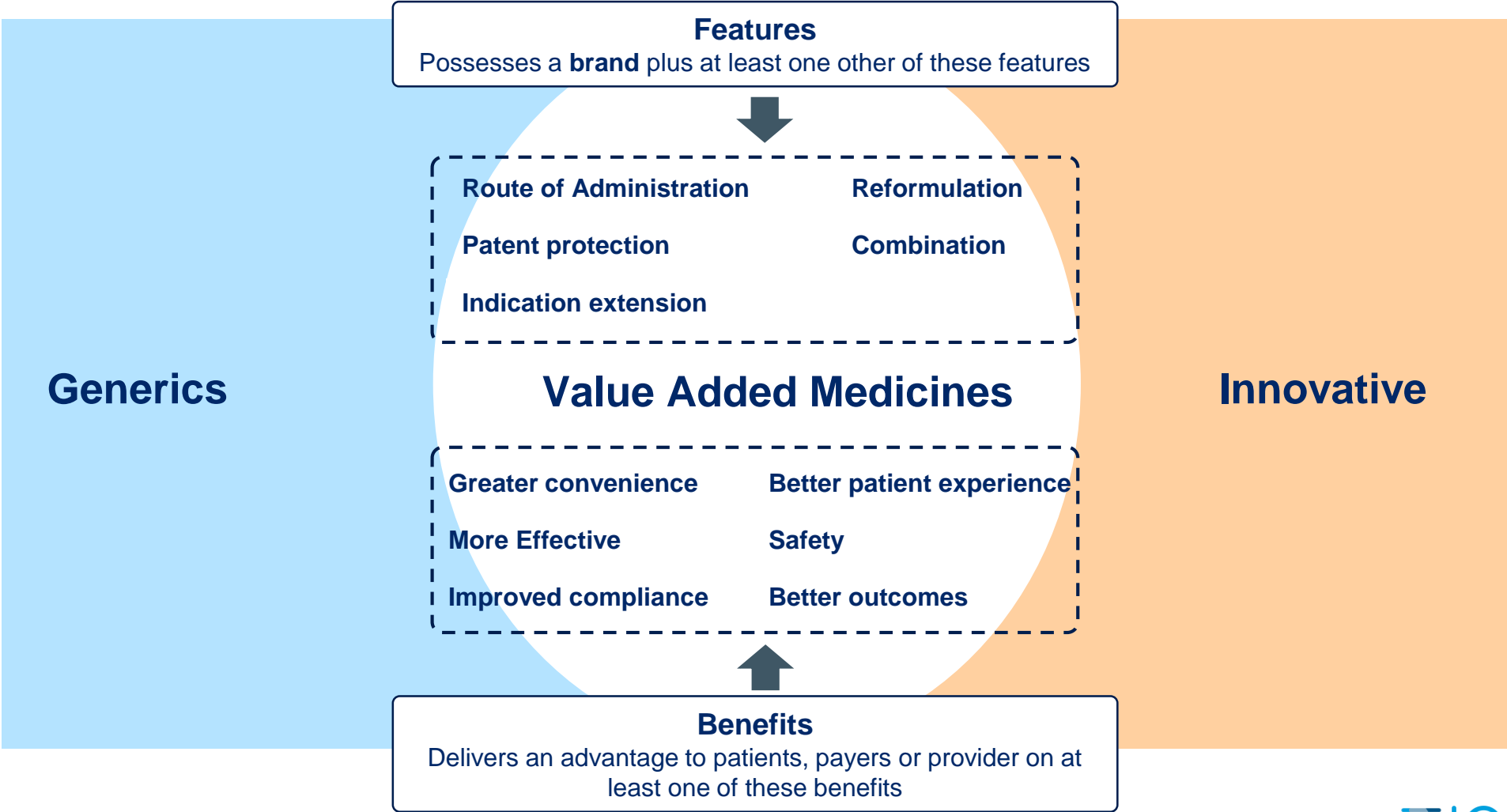
Compliance is undoubtedly the biggest source of inefficiency

- Volume driven by primary care products
- Efficacy is satisfied but Compliance remains a problem
- Generic products also do not appeal to patients in the way that branded products do
- Increasing benefits such as convenience and ease, combined with brand attractiveness can increase patient compliance

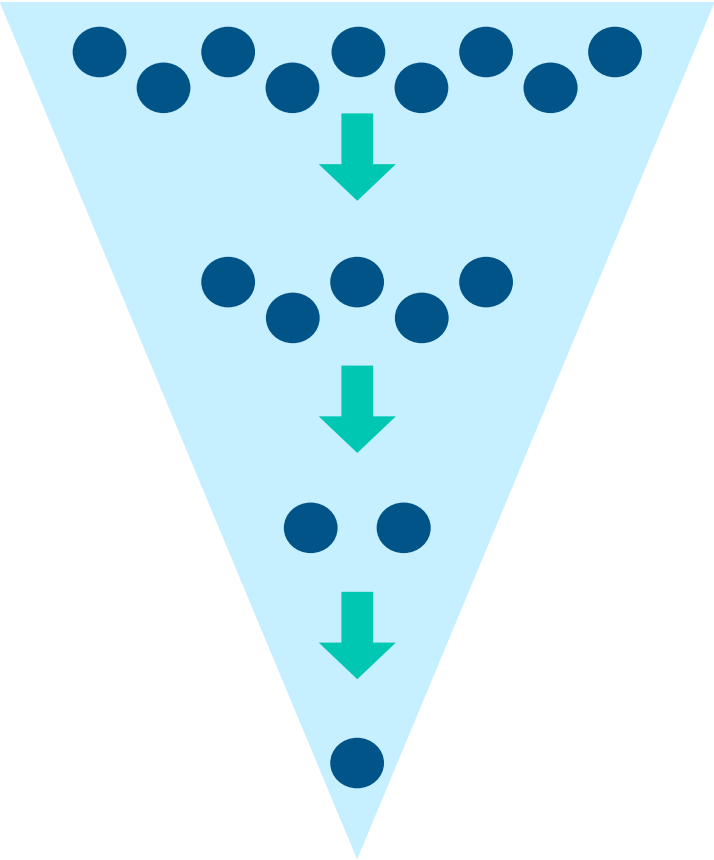
USA Estimated avoidable costs (2012) bn USD



IQVIA qualitative definition



IQVIA methodology to market sizing using MIDAS



IQVIA MIDAS Filters applied

Reason

Licensing Status = Other Brands
Protection = Protected, No Longer Protected, Unknown
Name Type = Branded

Not an originator and not licensed
 Product (not the molecule) has been or is currently protected
 Product is Branded

Excluding **Biologic** molecules
Patent expiry = Expired, Unknown

Non-original biologics and biosimilars are not Value Added Medicines
 Molecules are not patent protected

Added **Epipen**

Epipen is a Value Added product

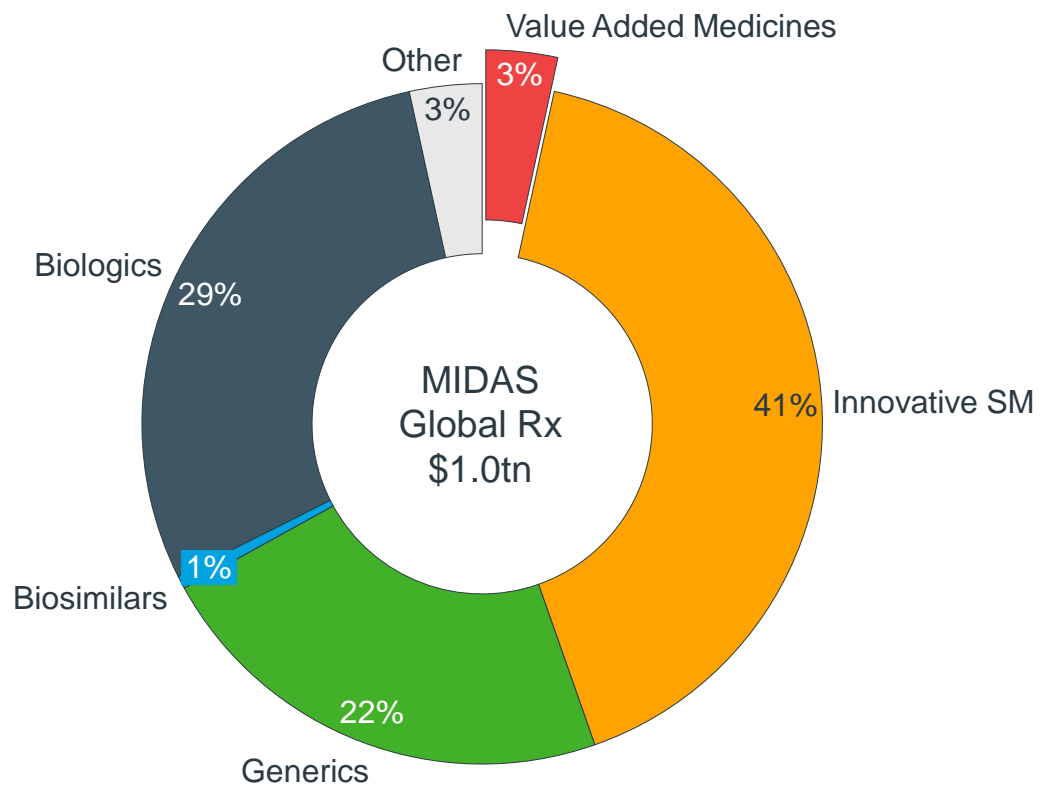
Methodology updated



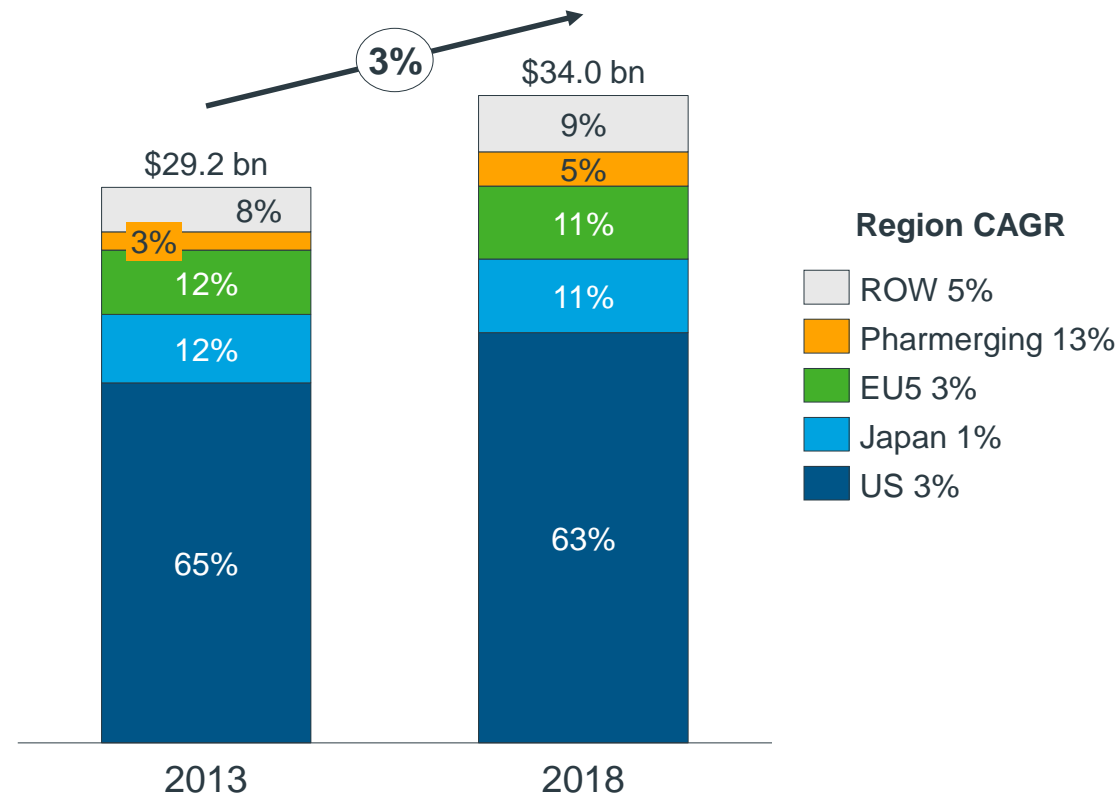
Pricing pressure in the US continues to stall growth in 2018

Pharmerging grows by 13% in 2018 driven by anti-HIV and Contraceptives

Global Rx Value (MAT Q2 2018) LCUSD

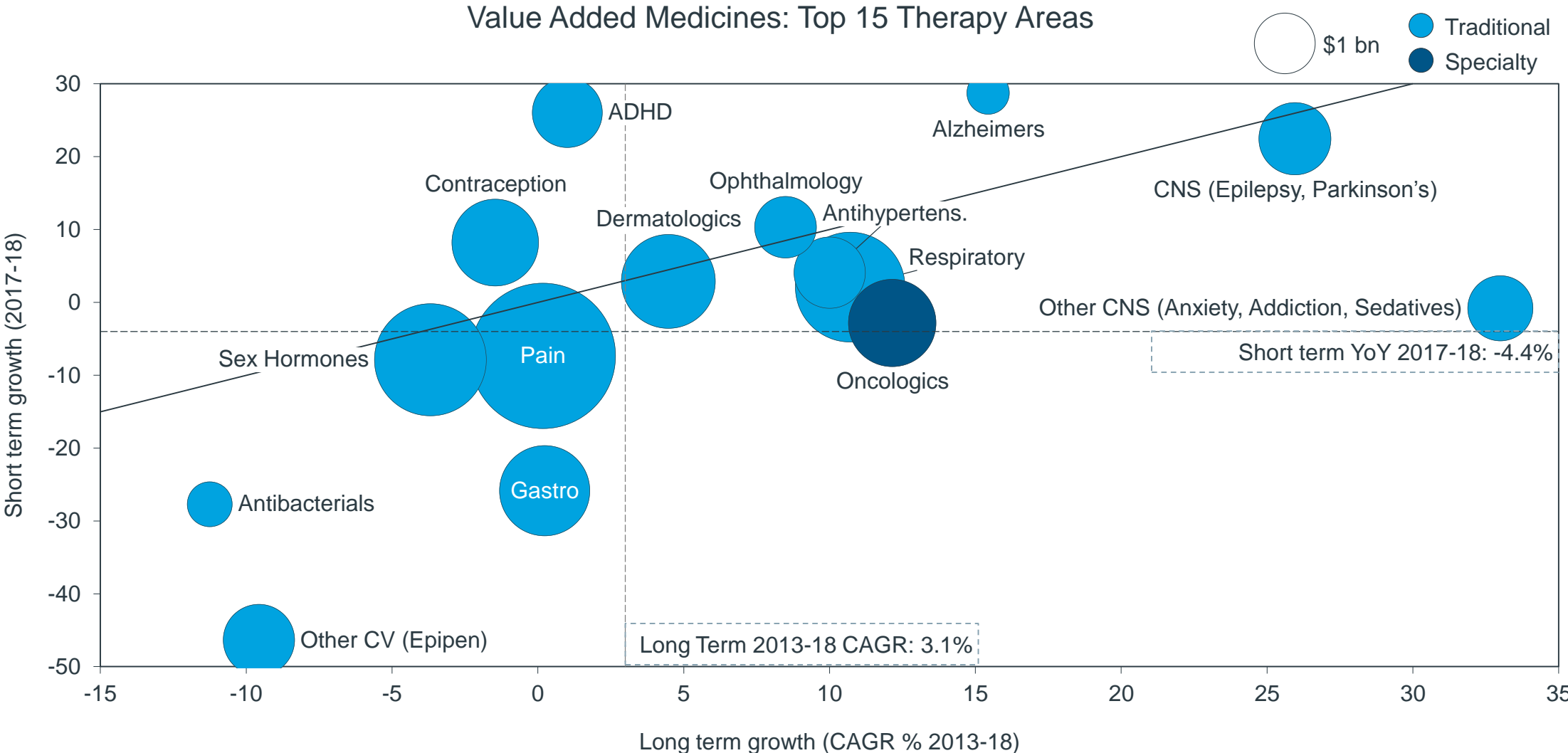


Value Added Medicines (MAT Q2 2018) LCUSD



Notes: Other includes Vaccines, Non-RX and Undefined products
Source: IQVIA European Thought Leadership Analysis; IQVIA MIDAS MAT Q2 2018; Rx only

CNS products have shown historical success



Source: IQVIA European Thought Leadership; IQVIA MIDAS MAT Q2 2018; Rx only



Value Added Medicines are truly global

Top Products (2018) Mn USD

USA

Salamol	1481	Respiratory
Duexis	1230	Pain
Androgel	1060	Sex Hormones
Premarin	880	Sex Hormones
Beclazone	765	Respiratory

EU5

Versatis	230	Pain
Targin	209	Pain
Ozurdex	183	Ophthalmology
Ambisome	175	Antifungals
Duodopa	140	CNS

China

Wei Kang Da	201	Oncologics
Shi Hui Da	168	Antihypertens.
Yi Li An	65	Anti-Ulcerants
Ou Sai	61	Adjuvants
Li Bi Fu	58	Adjuvants

Brazil

Mirena	52	Contraception
Annita	49	Parasitic
Exodus Ache	28	Mental Health
Elani	18	Contraception
Elani 28	16	Contraception

Japan

Sector	448	Pain
Lotriga	276	Other Cv
Artz	219	Pain
Reminyl	213	Alzheimers
Zacras Combo	144	Antihypertens.

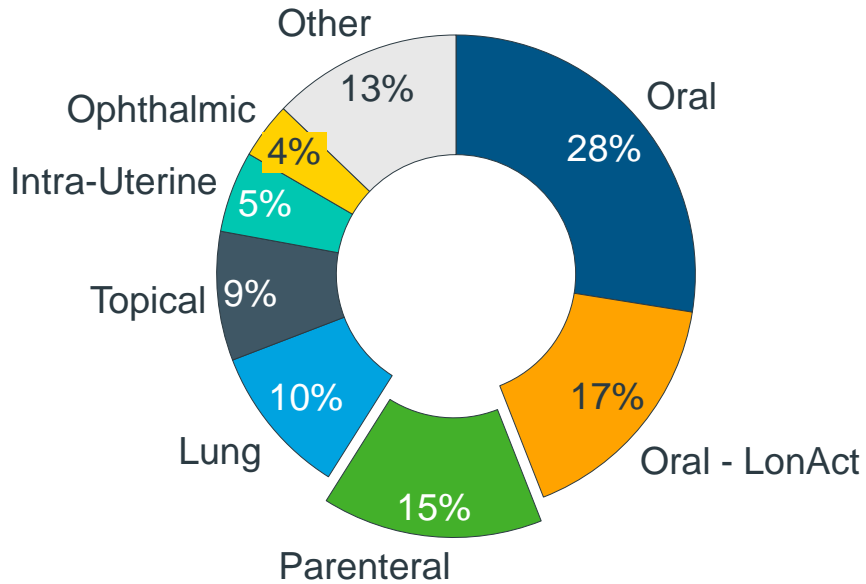


Top products vary by country as Value Added Medicines fulfil individual country needs



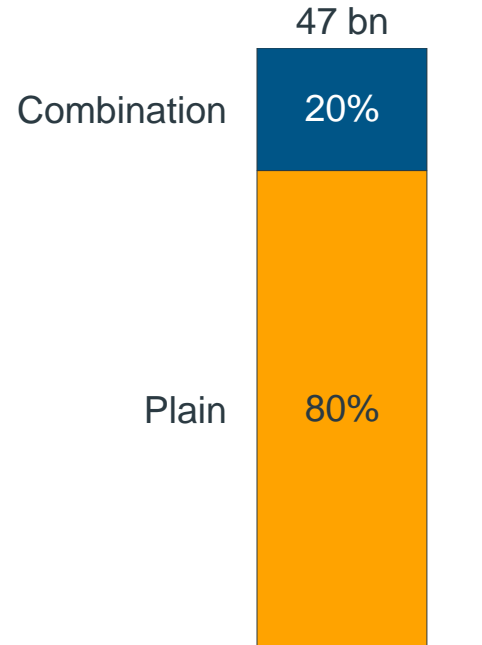
Oral solids make up over half the market

Admin route, Global (2017) LCUSD

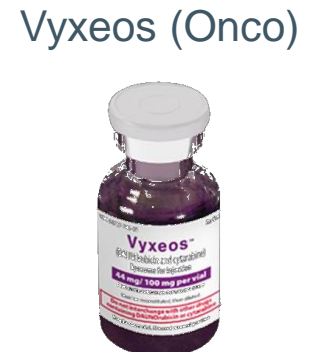
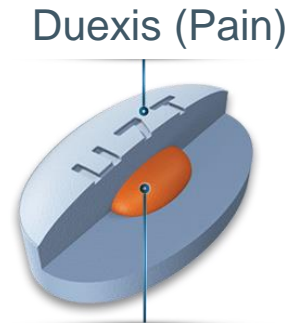


Injectables 5y CAGR 11%

Combination products Volume (SU)



Combination products can take various forms



Notes: Injectables defined as NFC2: Ampoules, Infusions, Pens & Cartridges, Prefilled Syringes and Vials
 Source: IQVIA European Thought Leadership Analysis; IQVIA MIDAS MAT Q2 2018; Rx only

Value Added Medicines products fall on a spectrum of innovation

Incremental innovation

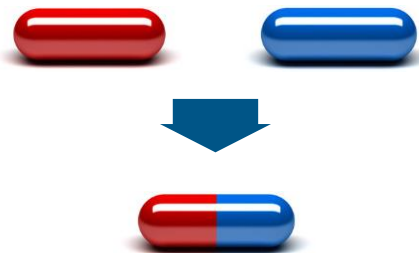
- Lower price premium
- Lower barrier to entry
- Lower R&D cost

High innovation

- Higher price premium
- Higher barrier to entry
- Higher R&D cost

Lower level innovation

- Combination
- Formulation
- Dermal patches



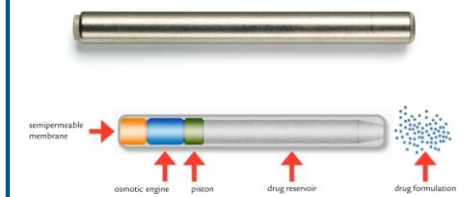
Incremental innovation

- Inhalers
- Auto-injectors



Novel delivery technologies

- Nanoparticles
- Microchips
- Minipumps

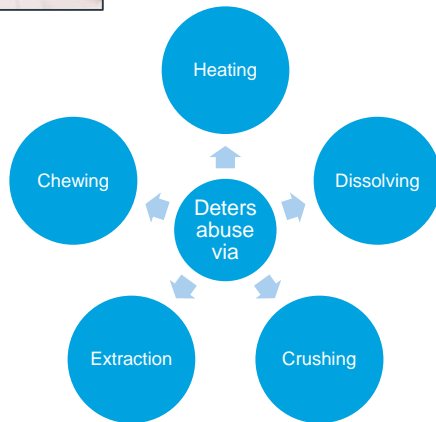


Thinking ahead: Innovative Solutions from MedTech companies

Lucideon's iCRT ceramic pills

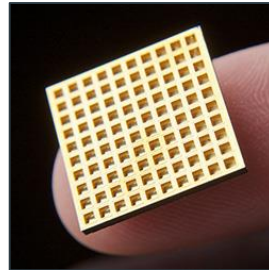


Problem: Opioid abuse epidemic
Drug: Opioid painkillers
Innovation: Ceramic pills
Outcome: Abuse deterrent



The ceramic technology allows restricted access to the opioids and can be tailored for slow release if needed. As the ceramic is extremely hard, it is resistant to crushing, heating, and chewing. Extraction using alcohol is also hindered.

Microchips Biotech's microchip



Problem: Daily injections
Drug: Parathyroid hormone
Innovation: Microchip implant
Outcome: Precise automated dosing

The microchip is a drug delivery device that can store hundreds of doses over years and release the drug at a precise time and dosage.

The device can be controlled by the patient or clinician via a wireless remote or loaded with a predetermined program.

There is a significant benefit to the patient in not having to inject on a daily basis and the clinician in preserving full control of the regimen.

Intarcia's Medici mini-pump



Problem: Daily injections
Drug: Exenatide (GLP-1)
Innovation: Mini-pump implant
Outcome: Convenient dosing

Intarcia's micropump needs re-implanting only once or twice a year and can deliver sustained daily dosing of exenatide, removing the need for daily injections.

Interestingly, Intarcia is trialling the technology for a exenatide, a drug that is currently under protection, showing a forward-looking approach to bringing the device to market.

Key takeaways

Fundamentals remain strong:
Adherence is a real unmet need

Value Added Medicines span a range of innovation which determines risk and reward

Medtech is booming and will introduce novel technologies into this sector

RWE: Communicate benefits effectively