The Data and Analytics of the New Life Sciences Marketplace

9th International Pharmaceutical Compliance Congress and Best Practices Forum

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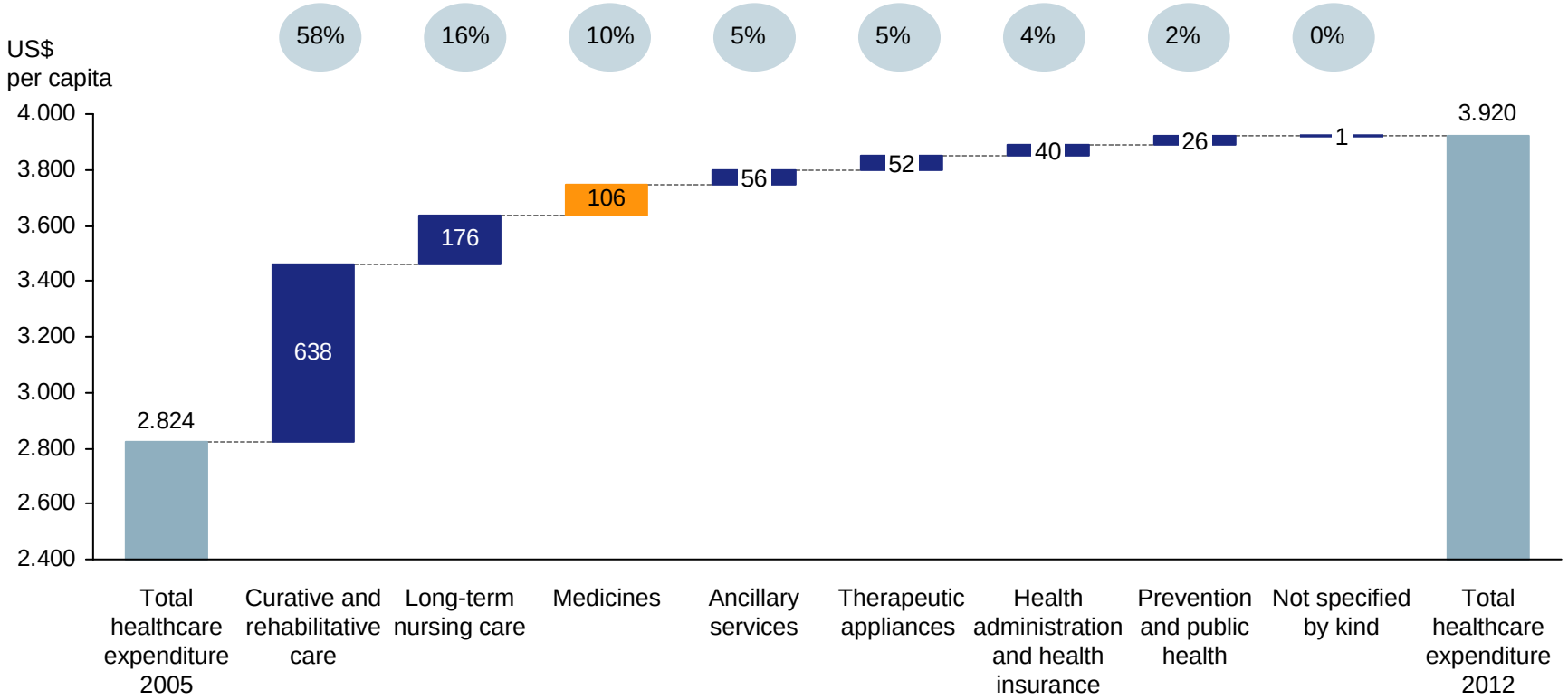
INTELLIGENCE APPLIED.

Governments must look beyond medicines for real efficiency gains

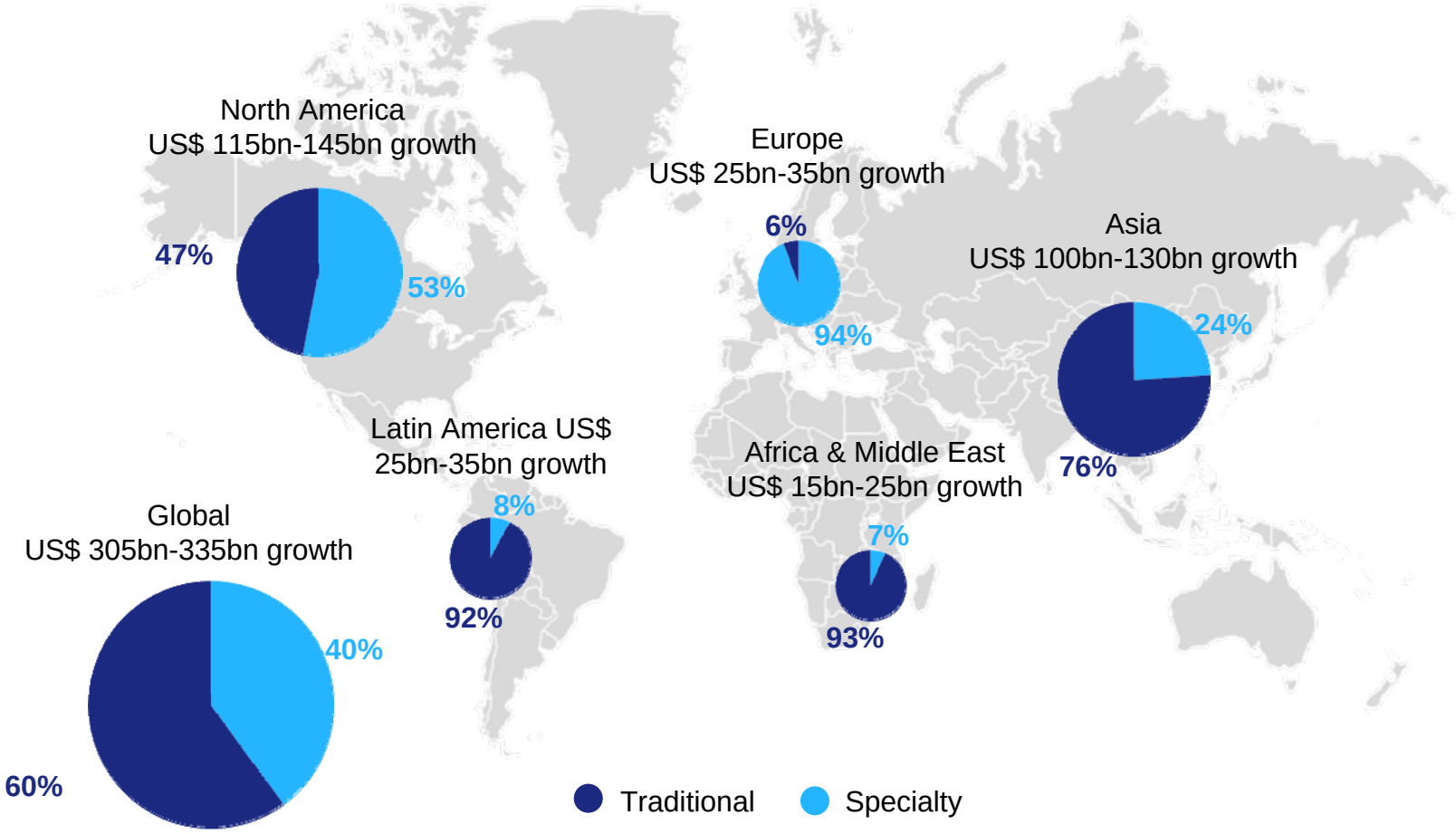
Share of Growth per healthcare category
(2005 – 2012, 15 EU OECD Countries*, population-weighted, current prices, PPP, $)



*Countries included: Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Luxembourg, Netherlands, Slovakia, Slovenia, Spain, Sweden
Source: OECD Health Statistics Database, Eurostat Database

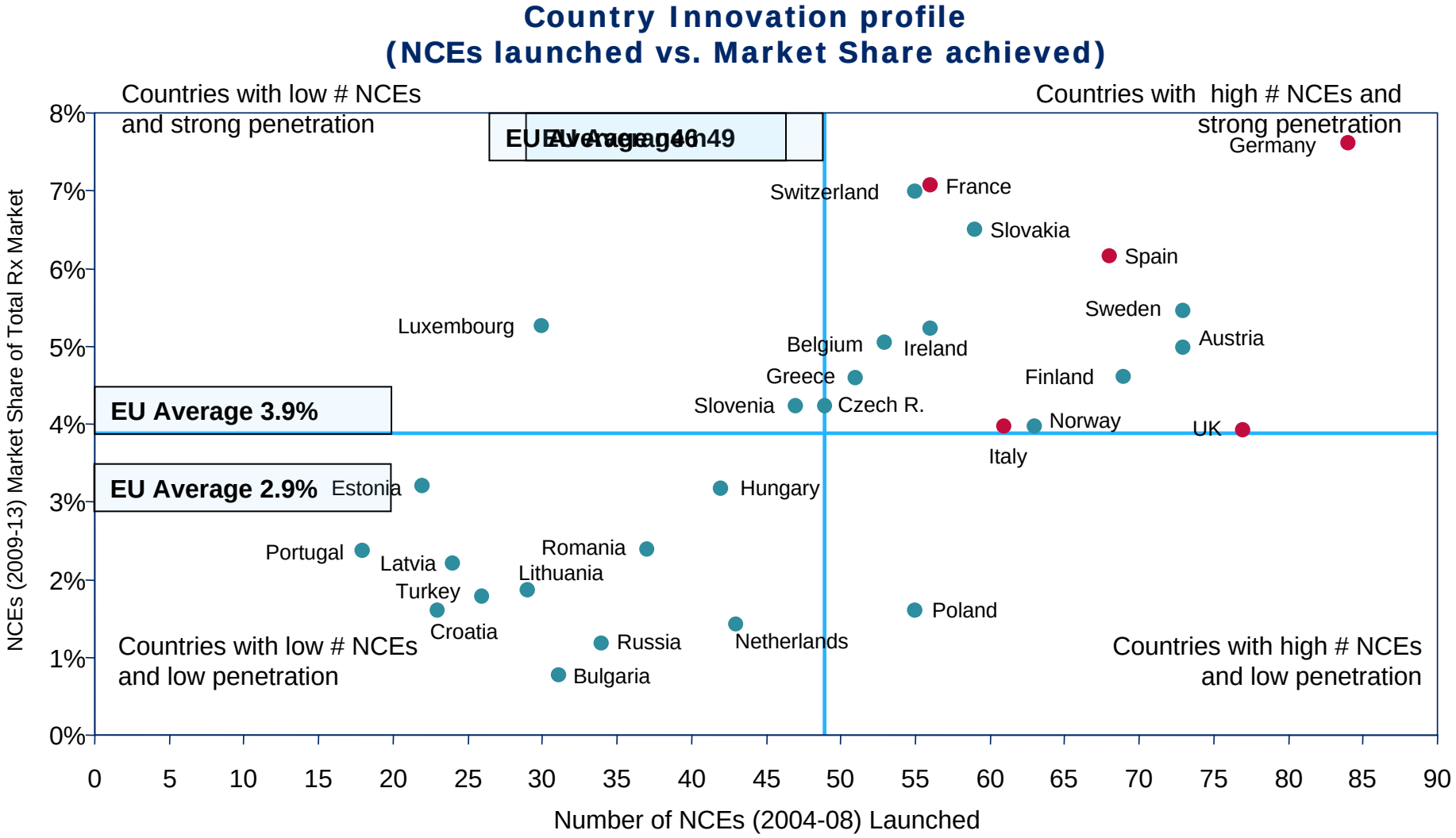
Specialty medicines drive growth in developed regions; globally, primary care dominates

Share of absolute growth 2013-2018 by region, specialty and traditional



Source: IMS Health Market Prognosis, September 2014; IMS Institute for Healthcare Informatics, Oktober 2014

EU countries vary significantly in the number and uptake of NCEs over the last years



Source: IMS Health, MIDAS, Year 2013, Rx only

EU5 Other Europeans

Europe illustrates the importance of biologic therapies

Europe Top 10 products 2009-14

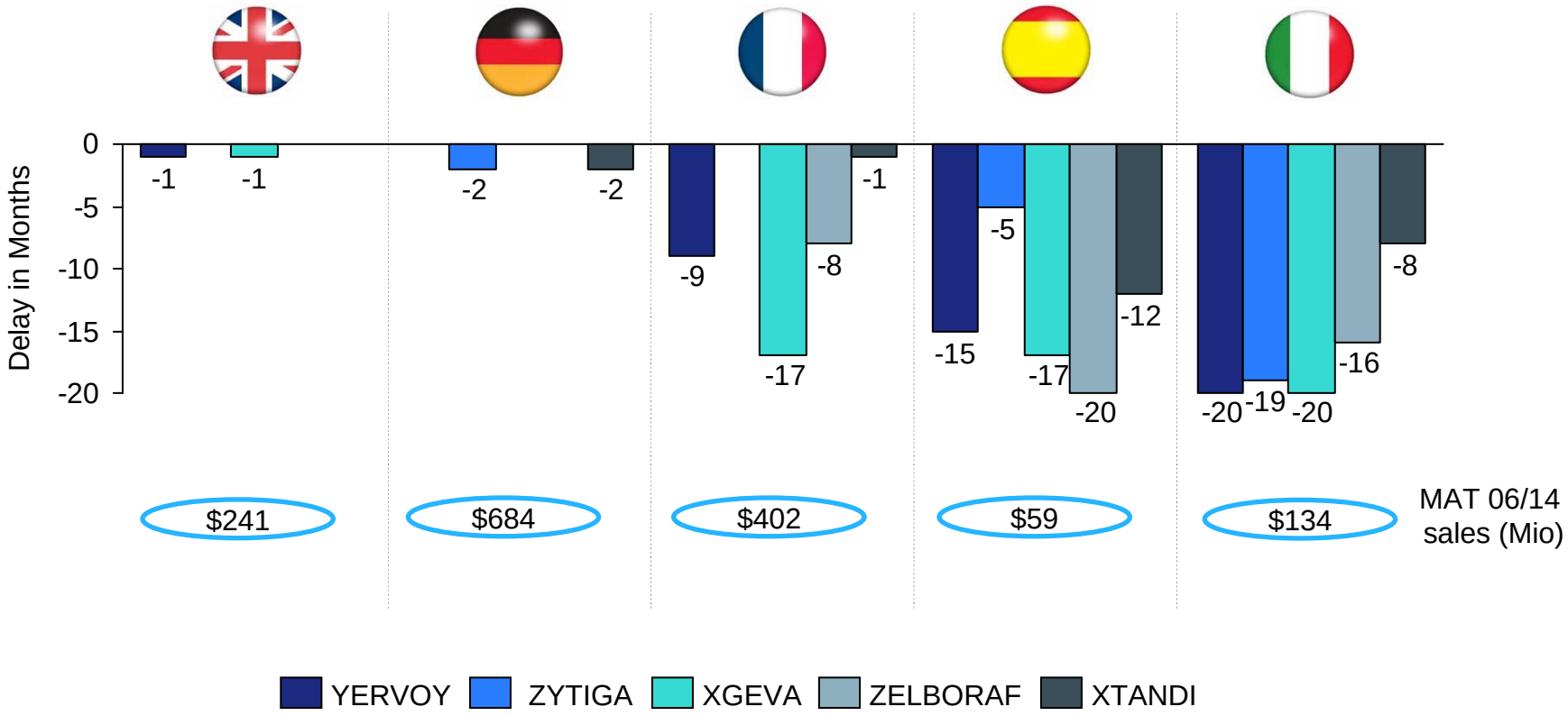
	2009	2010	2011	2012	2013	2014
1	LIPITOR	LIPITOR	LIPITOR	HUMIRA	HUMIRA	HUMIRA
2	SERETIDE	SERETIDE	SERETIDE	SERETIDE	SERETIDE	ENBREL
3	PLAVIX	HUMIRA	HUMIRA	ENBREL	ENBREL	SERETIDE
4	ENBREL	ENBREL	ENBREL	LIPITOR	HERCEPTIN	HERCEPTIN
5	HUMIRA	HERCEPTIN	HERCEPTIN	HERCEPTIN	MABTHERA	REMICADE
6	HERCEPTIN	LOVENOX	LOVENOX	LOVENOX	REMICADE	AVASTIN
7	LOVENOX	AVASTIN	AVASTIN	MABTHERA	LOVENOX	MABTHERA
8	ZYPREXA	ZYPREXA	MABTHERA	REMICADE	AVASTIN	LOVENOX
9	PANTOZOL	PLAVIX	REMICADE	AVASTIN	LUCENTIS	LYRICA
10	SYMBICORT	REMICADE	ZYPREXA	SPIRIVA	LYRICA	LUCENTIS

Small molecule products Biologic products

Source: IMS Health MIDAS, MAT June 2014, Rx bound. Europe does not include Russia and Turkey

Launch rollouts across EU5 diverge greatly: Germany is key

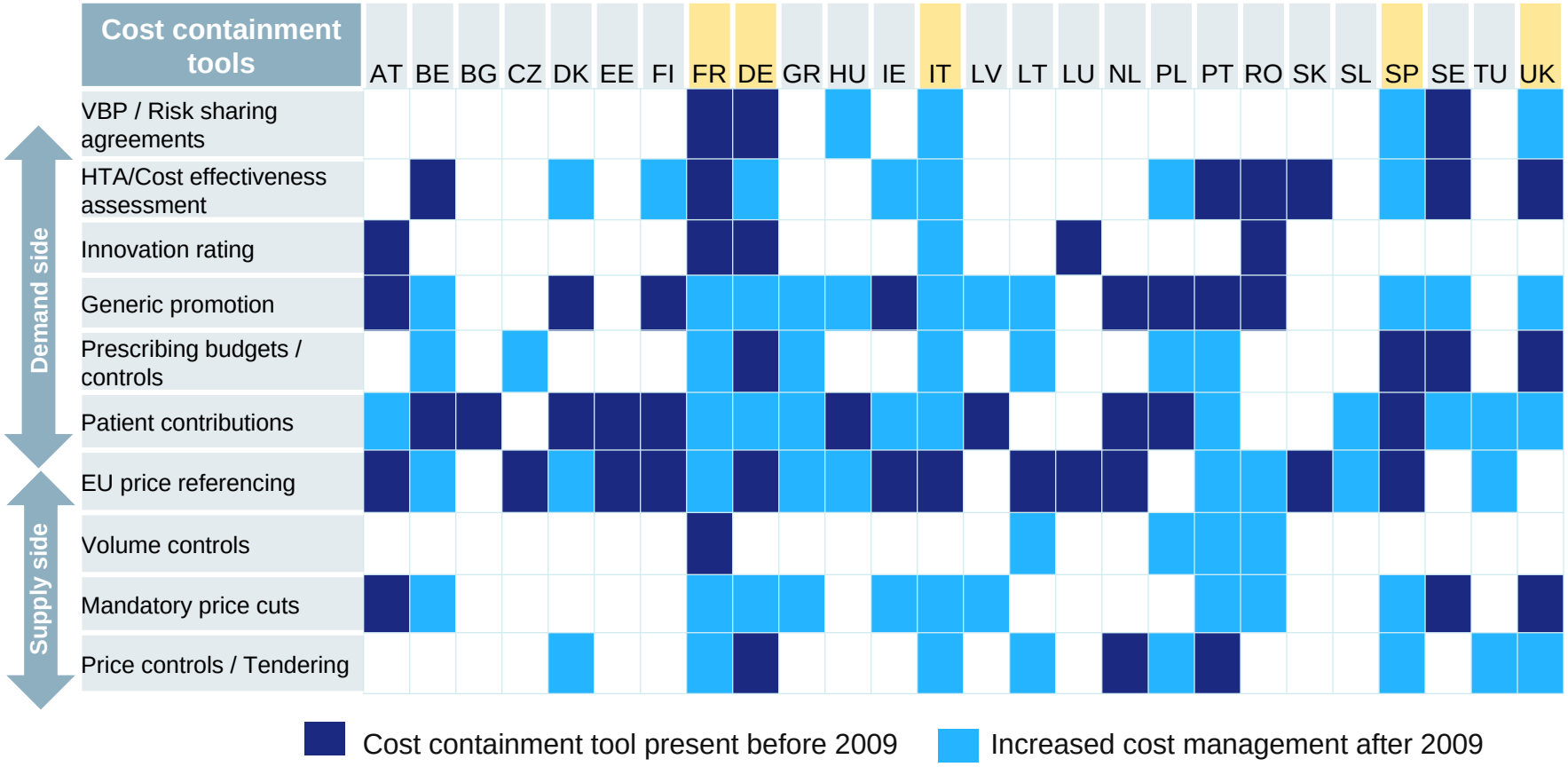
Top 5 onco drugs (since 2010), delay from 1st country's launch, EU5



Source: IMS Health, MIDAS monthly Jul 2014, Rx only. Delay calculated from 1st country's launch in one of the EU5 markets. Country ranked by months of delay since first launch; drugs ranked by first date of launch in one the EU5 markets.
Xtandi not launched yet in Spain (the 12 months equal the time between first launch and Jul'14

Before the crisis, most countries had implemented some cost containment measures

However, the frequency and strength of such measures has increased significantly



AT: Austria, BE: Belgium, BG: Bulgaria, CZ: Czech Republic, DK: Denmark, EE: Estonia, FI: Finland FR: France, DE: Germany, GR: Greece, HU: Hungary, IE: Ireland, IT: Italy, LV: Latvia, LT: Lithuania, LU: Luxembourg, NL: Netherlands, PL: Poland, PT: Portugal, RO: Romania, SK: Slovakia, SL: Slovenia, SP: Spain, SE: Sweden, TU: Turkey, UK: United Kingdom

In Europe, value plays an ever more important role as a criterion for pricing and reimbursement

EU5

Before launch

applied
applied indirectly

					
National regulatory authority	ANSM	BfArM, Paul-Ehrlich Institut	AIFA	AEMPS	MHRA
Price and reimbursement setting	Negotiation with transparency committee (within HAS), CEPS decides on reimbursement	Price setting through negotiation within one year after market launch	Negotiation with P&R committee, plus negotiation with regions	Negotiation with commission of prices of medicines, plus negotiation with regions	Free price setting within range in Pharmaceutical Price Regulation Scheme (PPRS), negotiation with CCGs
Value based pricing / HTA	Added therapeutic benefit as basis for negotiation	Benefit dossier mandatory for every new subst.	Value and innovation criteria in negotiation	Value considered for reimbursement decision	Value based assessment by NICE
EU price referencing	Prices should be similar to those in DE, ES, IT, UK	If no add. benefit, 15 European reference countries	Supportive decision criterion, average of reference countries	lowest price in EU ref. countries, 10-50% lower than ref. prod.	
Mandatory price cuts	Clawbacks, if cost of p.-v. agreement is exceeded	7% rebate for innovative medicines	Rebates when cap for reimb. med. spend. exceeded	7.5% rebate for new drugs, 4% rebate for orphan drugs	Price cut of 15% if not in PPRS
Price controls / tendering	Hospital care	Mainly generics and biosimilars	Generics, biosimilars	anti -TNFs and EPOS, some medicinal products	Hospital: Vaccines, communicable dis., pandemics
Risk sharing agreement	Higher price, after 2nd eval. maintain or pay back diff.	Since 2007 between manufacturer and insurance	Discount on initial therapy cycles, pre-set time frame	Reimbursement by manufacturer in case of failure	Patient access schemes

CEPS=Comité économique des produits de santé, HAS=Haute autorité de santé, CCGs=Clinical Commissioning Groups, NICE=National Institute for Health and Care Excellence
Source: Desktop research March 2015

National requirements for health economic evidence differ between P&R processes in EU-5

EU5

National level stakeholders and evidence requirements							
Key P&R decision-makers requiring direct engagement			CT, CEPS	G-BA, IQWiG, GKV-SpV	CTS, CPR (AIFA)	AEMPS, DGCBSF, CIPM	DoH, SMC, NICE
Evidence requirements	Clinical	Basic clinical trial data	✓	✓	✓	✓	✓
		Comparative clinical analysis	✓	✓	✓	✓	✓
	Economic	Basic pricing data	✓	✓	✓	✓	✓
		Budget impact data	*Health economic data is currently optional*	✓	✓	✓	✓
		Cost-effectiveness data		✗	✓	✓	✓

✓ Mandatory
✓ Not mandatory but recommended
✗ Not required

Source: Country-specific sources

In addition, various cost containment measures are implemented in most EU-5 countries

EU5

After launch

applied
applied indirectly

					
National spend ceiling	ONDAM set by parliament every year		Outpatient < 13% / overall < 16% of total healthcare exp.		
Prescribing budgets / controls	Indicative (plans to move to obligatory)	Obligatory	Indicative	Indicative	Indicative
Prescription quotas	Generics	Biosimilars			
Patient contributions	100%, 65%, 35% or 15% reimbursement	10% of price as contribution (min. 5€, max. 10€)	Depending on region 1-4€ / prescription	100%, 90%, 60% reimbursement	£8,05/prescription, £29,10/3 months, £104,10/12 months
Hospital procurement (in-patient)	Tendering, discounts possible	Tendering, discounts possible	Tendering, 50% mandatory discount	Tendering, discounts possible	Tendering, discounts possible
Generic promotion	Generic price link (60% less than orig.), generic substitution due to quota, substitution of certain biosimilars possible	10% mandatory rebate, generic substitution obligatory	Generic price link, generic substitution obligatory (including patient consent)	Generic price link, generic substitution obligatory (depends on price)	Students taught to prescribe by INN, subst. only allowed, if prescribed by INN

ONDAM=L'objectif national des dépenses d'assurance maladie, INN=International Non-Proprietary Name
Source: IMS Health March 2015

In Europe, most countries restrict biologic prescribing in rheumatoid arthritis

EU5

Different markets taking different approaches

The different levels of restriction placed on biologic prescribing in RA

Rheumatoid Arthritis

Limited restriction from guidelines but usage limited at a regional/local level	Guidelines not limiting access further than the label	Guidelines specifying situations in which biologics can be used
		
*Prescribing of biologics in RA is limited to hospitals and prescription by a specialist**	*National RA guidelines specify biologic use only after failure on MTX optimal dose but without multiple DMARD use*	*National RA guidelines specify biologic use only after failure on multiple DMARDs including MTX*

Source: IMS internal expertise, country specific websites. *this may vary by region, some regions may have further guidelines

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Payers have identified diabetes as a budget management priority in Europe

The challenge will be positioning and sustained evidence

Diabetes is a Top 5 budget item for EU payers because of size and volume growth and the premium pricing of new products

Lack of generic respite in future market

Expected # of future launches

Diabetes has become a top management priority for EU payers

Impact on new launches

- Increased **scrutiny of clinical and HECON data** in pricing and reimbursement negotiations
- **Increased demand for incremental improvements** in efficacy and safety data from 2nd, 3rd. 4th to market launches
- **Increased use of access restrictions** from national / regional payers

Impact on inline products

- Increased push to use insulins as last resort in T2D through protocols and guidelines
- **Push** for pharmacists and hospitals to negotiate **larger rebates and discounts** from competitive ATCs

European regulators and payers have taken unprecedented measures against Sovaldi

EU5

Agreement to refund the cost of Sovaldi for any patient not cured; this type of agreement is **not common** in France

Confidential discount with some sickfunds prior to the GKV-SpV negotiation outcome, which is **ground-breaking**

NHS England have delayed Sovaldi's introduction by 4 months; this is **unprecedented**

MSSSI set population maximum expenditure caps for each recent innovative HCV launch separately (€125M/year for Sovaldi)

AIFA set up an ad hoc fund of €750mn to treat a maximum of 50,000 patients with Sovaldi in 2015

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Relative „value“ assessments are used to justify price and/or reimbursement

… but there are NO systematic methodologies YET to appraise value and link it to prrice in any HTA system

Recent EU5 developments suggest move towards value based pricing

- ove to adopt ITR system delayed
- aw back on free pricing and refining orphan drug assessment
- ove to adopt a new innovation algorithm delayed
- ill no agreement on value based assessment

Key challenges facing value based HTA process

1. **Assessment** of clinical and economic value
2. **Appraisal** of value
3. Price and access **decision**

In the EU, there is a move towards harmonizing technical assessments

Early dialogue with regulatory bodies

Scientific **advice** in place with regulatory agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

eunethta

Move towards **parallel, centralised** Regulatory + HTA advice

Early dialogue with HTA bodies

Individual national HTA **advice** (e.g. NICE, GBA, AIFA) widely sought

- Provide HTA **advice to** define **relevant evidence and try to accelerate time to access**
- Stakeholders discuss the planned development early, including **patient populations, comparators, trial design, endpoints**,

Recent most successful launches are mostly specialist and for focused patient populations

EU launch successes are specialist lead, often for smaller patient populations

Achieving >$540mn within 5 years of launch* MAT 06 2014:

Zytiga (J&J)
Aug 2011
($1.07bn)

Gilenya
(Novartis)
Feb 2011
($817mn)

Victoza (Novo Nordisk)
July 2009
($554mn)

Prolia/Xgeva
(Amgen/GSK)
June 2010
($540mn)

Achieving >$400mn within 5 years of launch* MAT 6 2014:

Invega Sustenna (J&J)
April 2011
($536mn)

Simponi (J&J / MSD)
October 2009
($536mn)

Eylea (Bayer/Regeneron)
Launch October 2012
($462mn)

Afinitor (Novartis)
Aug 2009
($424mn)

All launched into areas of high unmet need:
- Prostate Cancer
- Multiple Sclerosis
- Diabetes
- Rheumatoid / Psoriatic Arthritis
- Antipsychotic depot formulation
- Osteoporosis
- Hep C
- Macular Degeneration

Specialty Products dominate

Source: IMS MIDAS June 2014

Question is… are we defining value in the same way?

Pharma Exec

Payer Exec

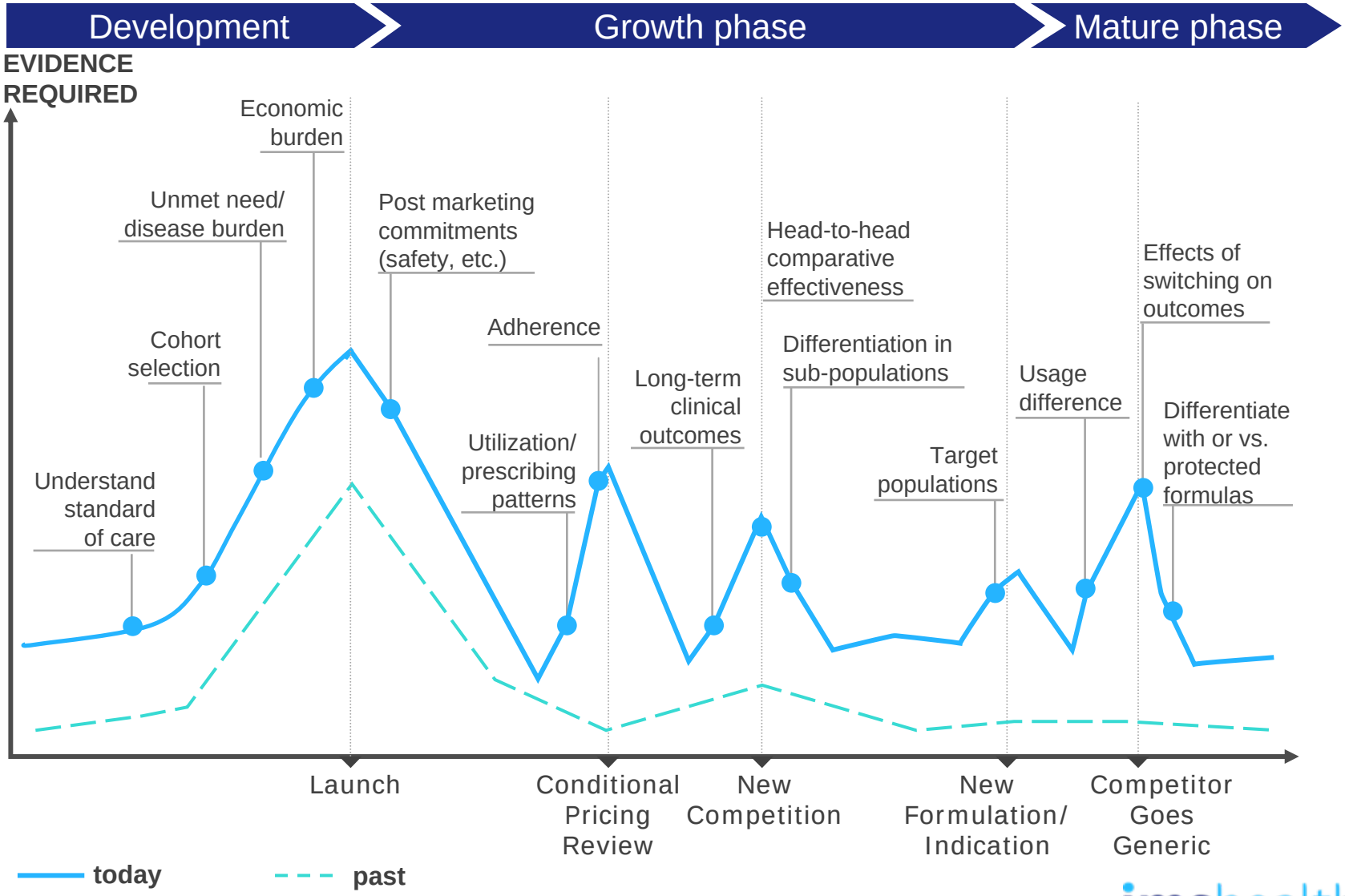
Product X Launches in Category Y

*"**PRODUCT X** had one of the largest clinical programs ever. Today's approval for this devastating disease is **significant for patients and physicians**, since the launch of CATEGORY Y products over a decade ago."* – Senior Executive

*"**Not all drugs need to be covered**. There are a number of choices in some classes like CATEGORY Y, with **many products costing more with no additional health benefit**."* – US PBM

Source: Fiercepharma.com; „Product X" investor relations

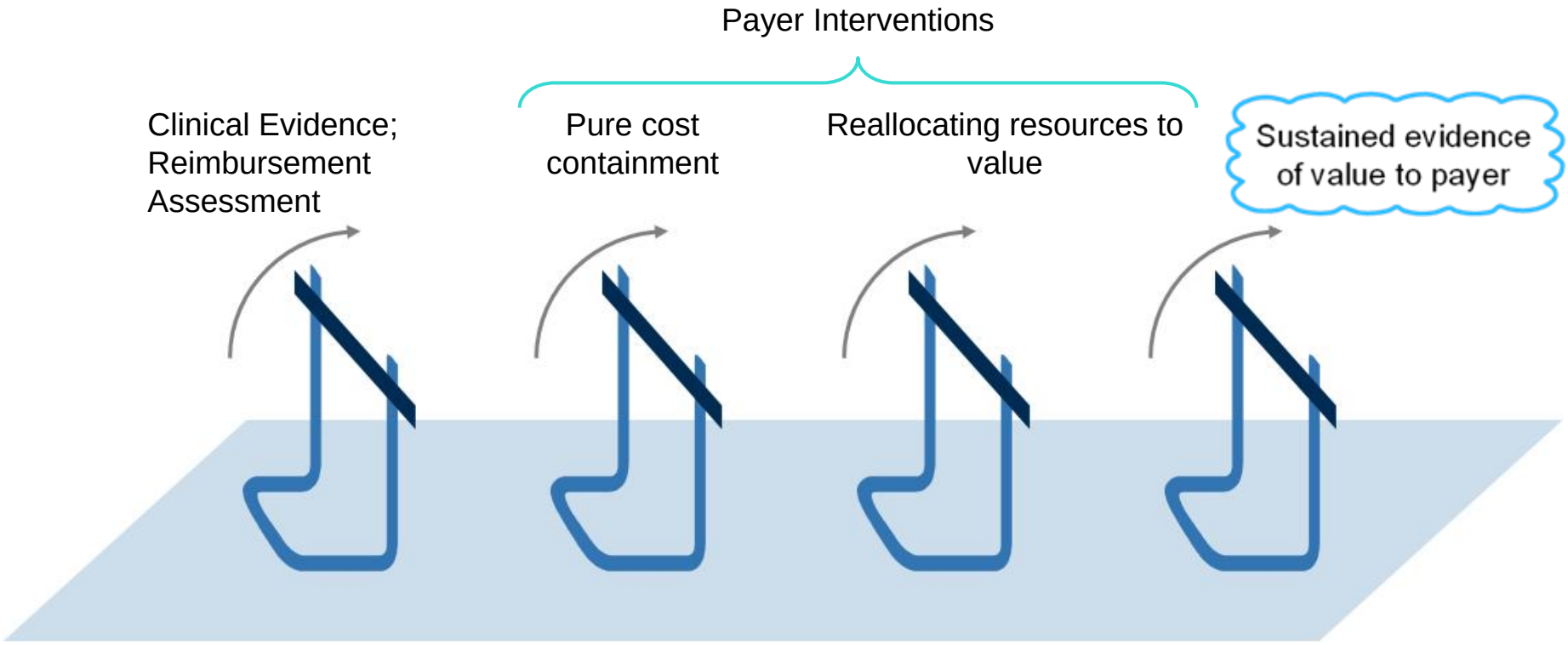
Real World Evidence can now be an essential value driver



Disputes over price versus value is the biggest challenge for Pharma in developed markets

Price	Additional clinical benefit is not the only factor that influences prices, context is key
Symptoms	While relieving unaddressed symptoms is a common field of play, curing a disease or restraining its progression would change perceptions and interaction with payers
Standard of care	SoC varies between and within countries. Patient behaviors can also influence value propositions. Think nationally but invest locally.
Public/payer perception	Greater communication is needed. Pharma shouldn´t be regarded as a pill supplier but as an integrated part of healthcare
Evidence/ RWE	Sustained evidence is critical to supporting the value proposition and thanks to the explosion in data sources the opportunity has never been greater

A restricted funding environment challenges Pharma to demonstrate value



Clinical evidence stricter at both regulatory and national reimbursement levels:
Payers demand H2H comparisons, addressing unmet need

Payers' increasing cost containment measures to balance and prioritise budget spend

Tangible and measurable incremental benefit

Addresses healthcare priorities

Pharma increasingly having to find common ground to achieve or sustain access

Efficiency and cost saving needs will drive healthcare to more virtual service

By 2020 virtual consultations may exceed face to face

Industries	*Healthcare* 	*Mobile phones* 	*MHealth* 	***Changing physician-patient-pharma engagement***
Products	*Sensors* 	*Internet* 	*Remote monitoring* 	***Less number of general visits and more..***

"Targeted investment in healthcare technology can deliver both better care for patients, whilst at the same time freeing up more money to provide that care…"

Dr. Dan Poulter, UK Health minister, Nov 2014

*March 2014 - British **hospital to become first** in Europe to use **Skype for consultations.** GPs are also being encouraged to introduce e-consultations to patients as part of the £50m GP Challenge Fund.*

Tomorrow is likely to see the rise of new mechanisms to limit spending growth

1. In the next 5 years there will be a dramatically reduced level of savings from shifting usage to generics
2. Are payers prepared adequately to cope with growing demand?... the patent 'dividend' is declining
3. If payers take holistic view of healthcare budgets they may be selective in allowing access to innovation
4. If they savings ignored across healthcare, actions will place more severe limits on access or prices for innovative medicines
5. If there are more restrictions on innovation, the consequence could mean higher healthcare costs in the medium term
6. In any of these scenarios, manufacturers can expect new mechanisms to limit spending growth, and innovation will suffer

Source: Harbingers of change in healthcare: Implications for the role and use of medicines

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