

## A call for action for Global and Regional MA: facilitate local payer engagement

*Prepared for Eye for Pharma 2015*

*Amsterdam, June 3<sup>rd</sup> 2015*

# Evaluating innovation: are payers putting a rope around their neck?



**NICE** National Institute for  
Health and Care Excellence

NICE guidance recommends sofosbuvir (Sovaldi, Gilead Sciences) and simeprevir (Olysio, Janssen) for treating hepatitis C

## **ICERs recommended:**

Genotype 1: £17,500 per QALY treatment naïve patients\*

Genotype 2: £12,500 per QALY treatment experienced\*\*

Genotype 3: £19,000 per QALY treatment experienced\*\*

Genotype 4,5,6: £20,000 - £30,000 per QALY gained\*\*\*

*“[...] offering Sovaldi via the NHS would put 20,000 patients in line for treatment. That's where the problem lies. **It's not a price problem, but a cost-burden problem.**”*

*Pharmafile<sup>2</sup>*

**FiercePharma**

**Sovaldi may be cost-effective, but the U.K. can't afford it, documents say**

October 7, 2014 | By Tracy Staton

1: [www.nice.org.uk](http://www.nice.org.uk) (2015-02-27)  
2: [www.fiercepharma.com](http://www.fiercepharma.com) (2014-10-07)

\*sofosbuvir plus peginterferon and ribavirin compared with peginterferon and ribavirin

\*\*sofosbuvir plus ribavirin compared with peginterferon and ribavirin

\*\*\*all patients with cirrhosis

# Payer engagement: is pharma ready for win-win solutions?

## Patents for Gilead's hepatitis C therapy Sovaldi challenged in five countries

(Ref: The New York Times, PR Newswire, CNBC)

May 20th, 2015

By: Joe Barber

*"by freeing [Sovaldi] from unjustified patents, we can fight this deadly disease and get more people the medicine they need to live healthy, productive lives."*

*I-MAK co-founder Priti Radhakrishnan<sup>1</sup>*

« WHERE BUSINESS MEETS POLICY »

# PharmExec.com

*"The one big miss is the reputational hit that Gilead took from US Medicaid and PBMs for its decisions on pricing, in which it was alleged the company **failed to reach out in a timely manner to help them prepare for the financial impact**....the bigger challenge was accurately assessing demand for the product"*

*William Looney is Pharm Exec's Editor-in-Chief*

- (Bloomberg via NewsPoints Desk)

## Gilead's Gaffe Leads Drugmakers to Pledge More Openness on Price

(Bloomberg via NewsPoints Desk)

(Ref: Bloomberg)

May 4th, 2015

*"If something works, you can figure out the business model, all we need to do is move the discussion upfront so that we're not reactive and we don't get caught in the Sovaldi situation."*

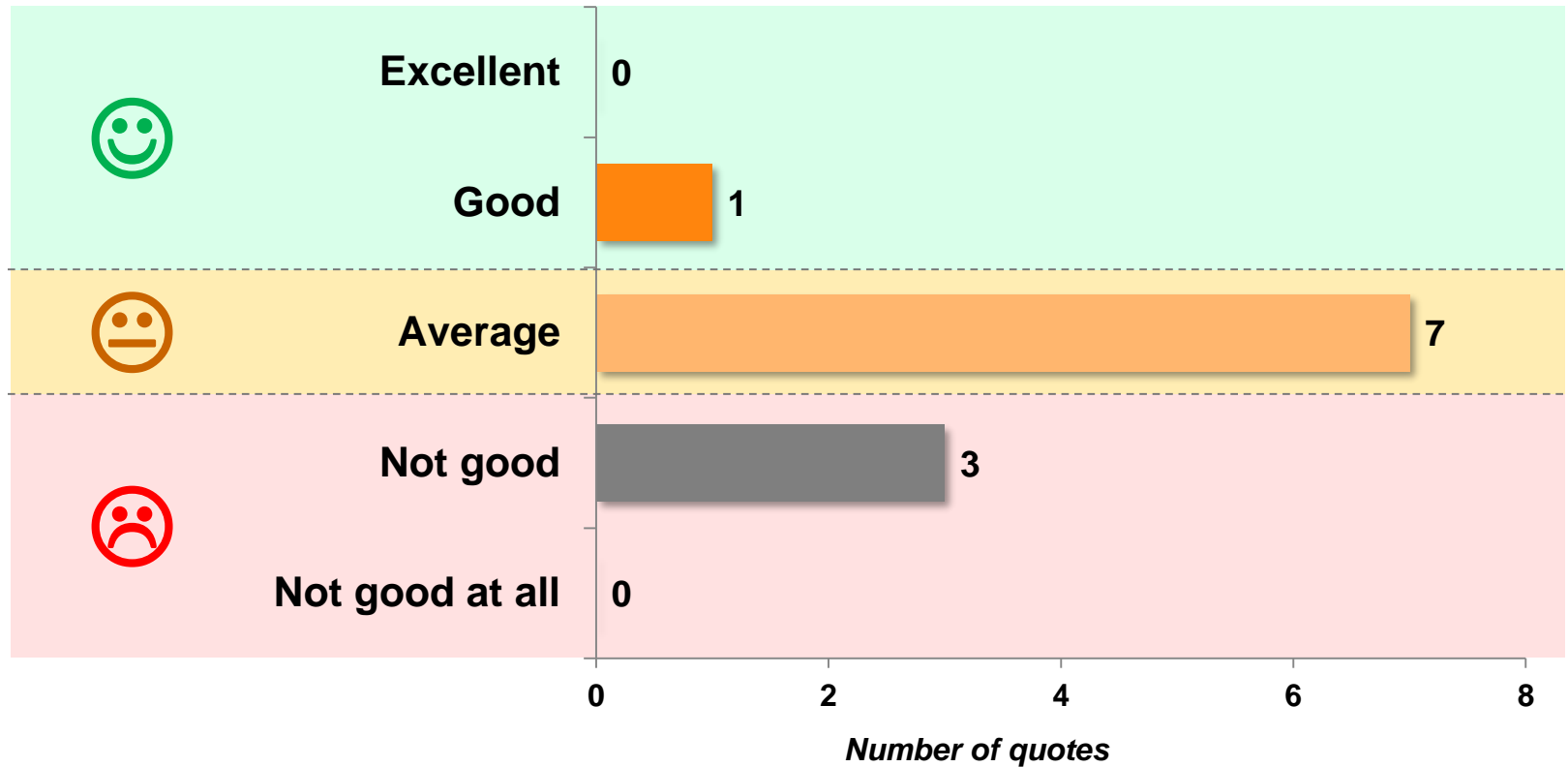
*David Meeker, CEO of Sanofi's Genzyme unit<sup>2</sup>*

1: [www.firstwordpharma.com](http://www.firstwordpharma.com) (2015-05-20)

2: [www.bloomberg.com](http://www.bloomberg.com) (2015-05-04) nness-on-price

# Payers perceive engagement with pharmaceutical companies of average quality

Q. How well do pharmaceutical companies perform in payer engagement?

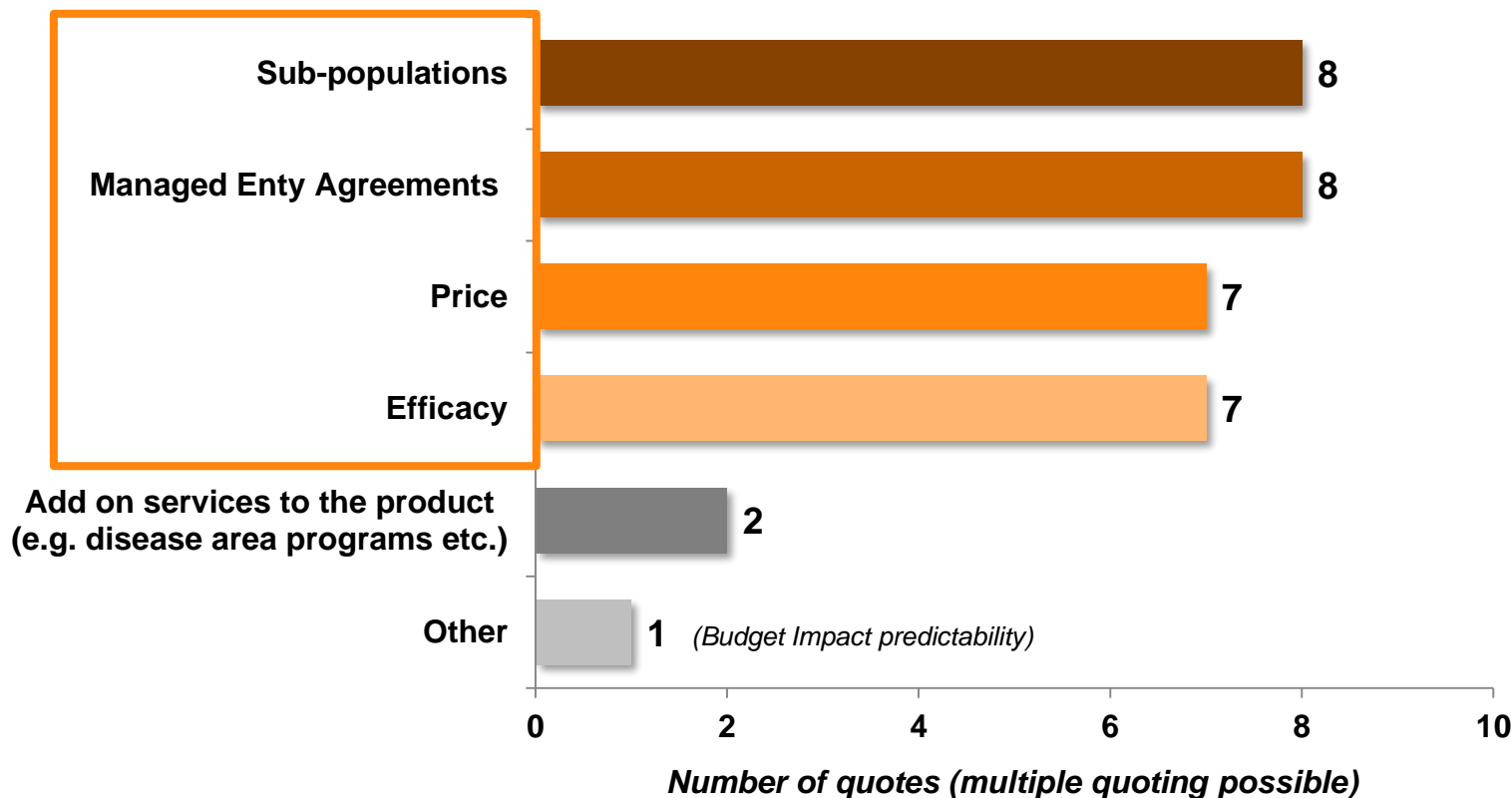


Source: Internet based survey with selected members of Executive Insight Payer Panel (n=11)

**What can be done to improve perception?**

# While the nature of what payers need is still centred in how to obtain more value for money...

Q. What topics are payers open to discuss with pharmaceutical companies?

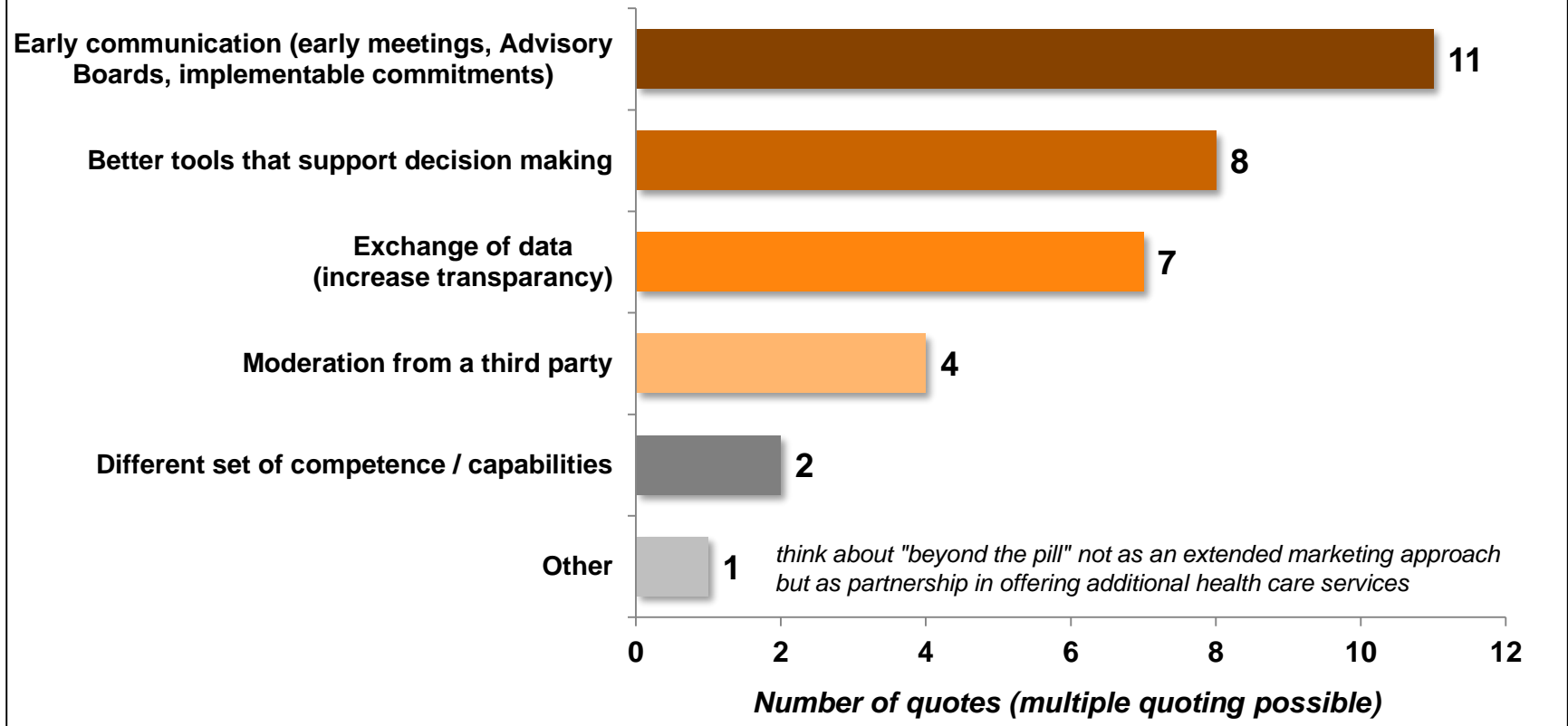


Source: Internet based survey with selected members of Executive Insight Payer Panel (n=11)

More alignment on the same topics?

## ... a different approach to payers engagement is needed

Q. What approach should be used to facilitate payer engagement?



Source: Internet based survey with selected members of Executive Insight Payer Panel (n=11)

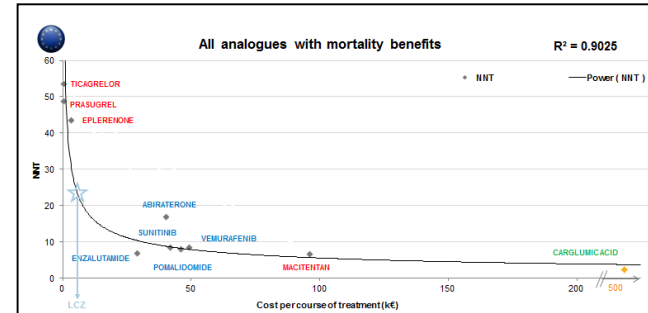
How early / proactive do we engage payers along the lifecycle?



























# Payer Engagement: a framework

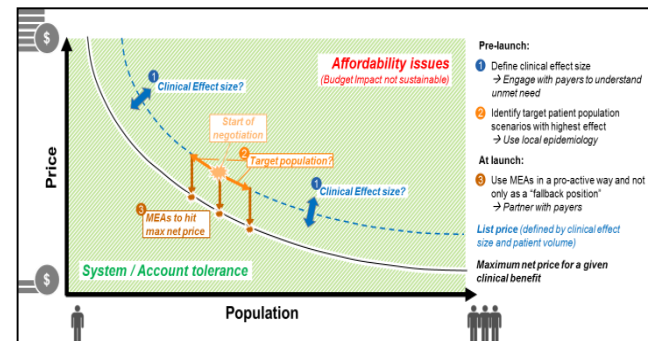
1<sup>st</sup> Inform  
payer  
referencing

2<sup>nd</sup> Address  
uncertainties

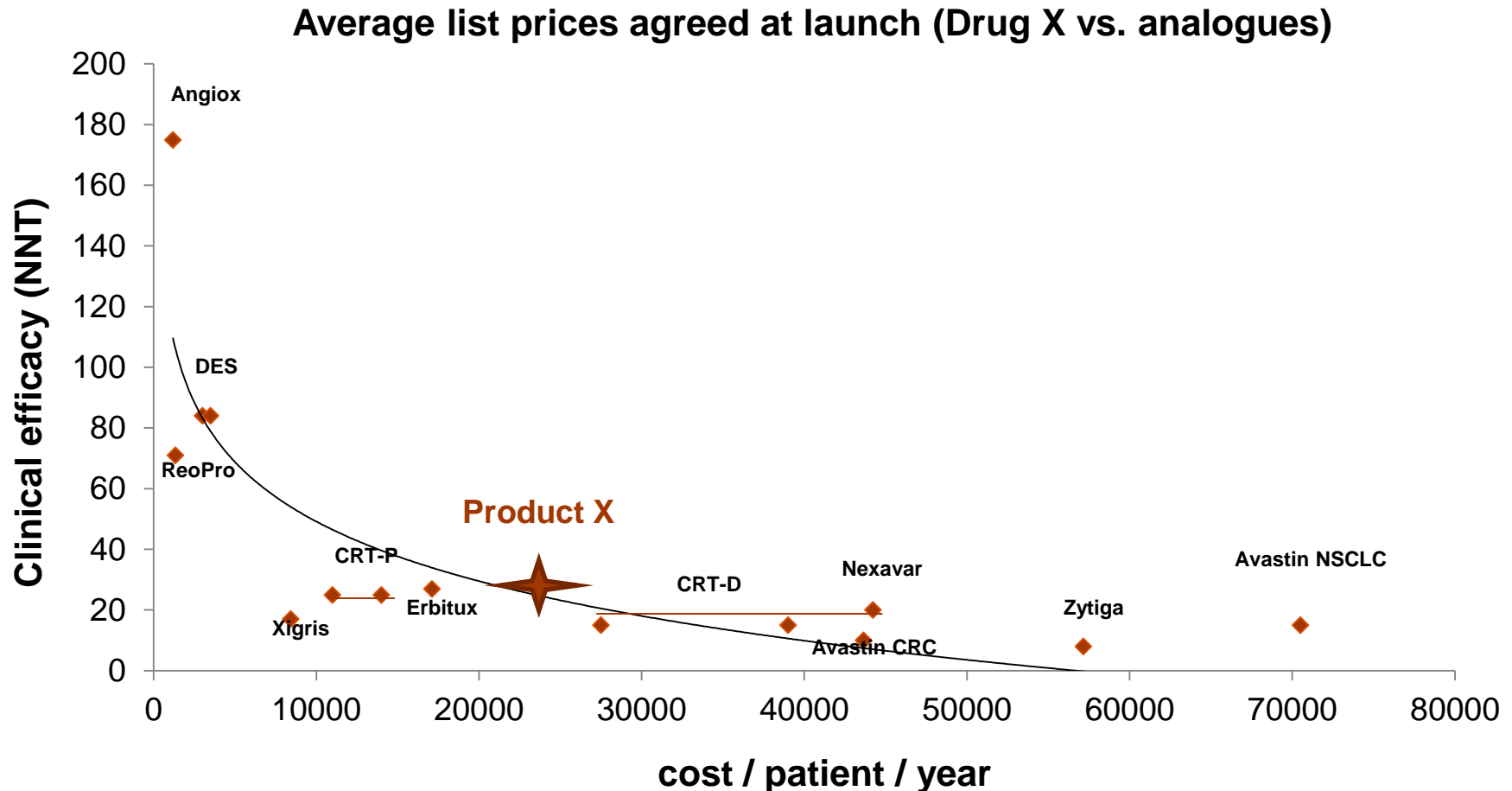
3<sup>rd</sup>  
Maximizing  
value for  
money



		 First option to be avoided	 Potentially useful					 Implemented requested but not commended		
		MEAs	Financial based schemes					Performance based		Value Added Services
		Undiscounted rebates	PVA	Cap per patient	Population capping	Portfolio Trade-Offs	Free initiation	Rebate on non-responders	Outcome Achievement based pricing	
Product X Challenges	Physician use in 1 <sup>st</sup> line									
	Uncertainty in the # of patients vs less expensive alternatives									
	Use in overlapping patient group									
Uncertainty about clinical or cost-effectiveness	Uncertainty of the superior efficacy									
	Believe that competitor is more cost-effective / cost-saving									
	Uncertainty that cost-savings are possible in the long term									
Affordability	Most expensive drug									
	The disease is a key focus of cost containment									



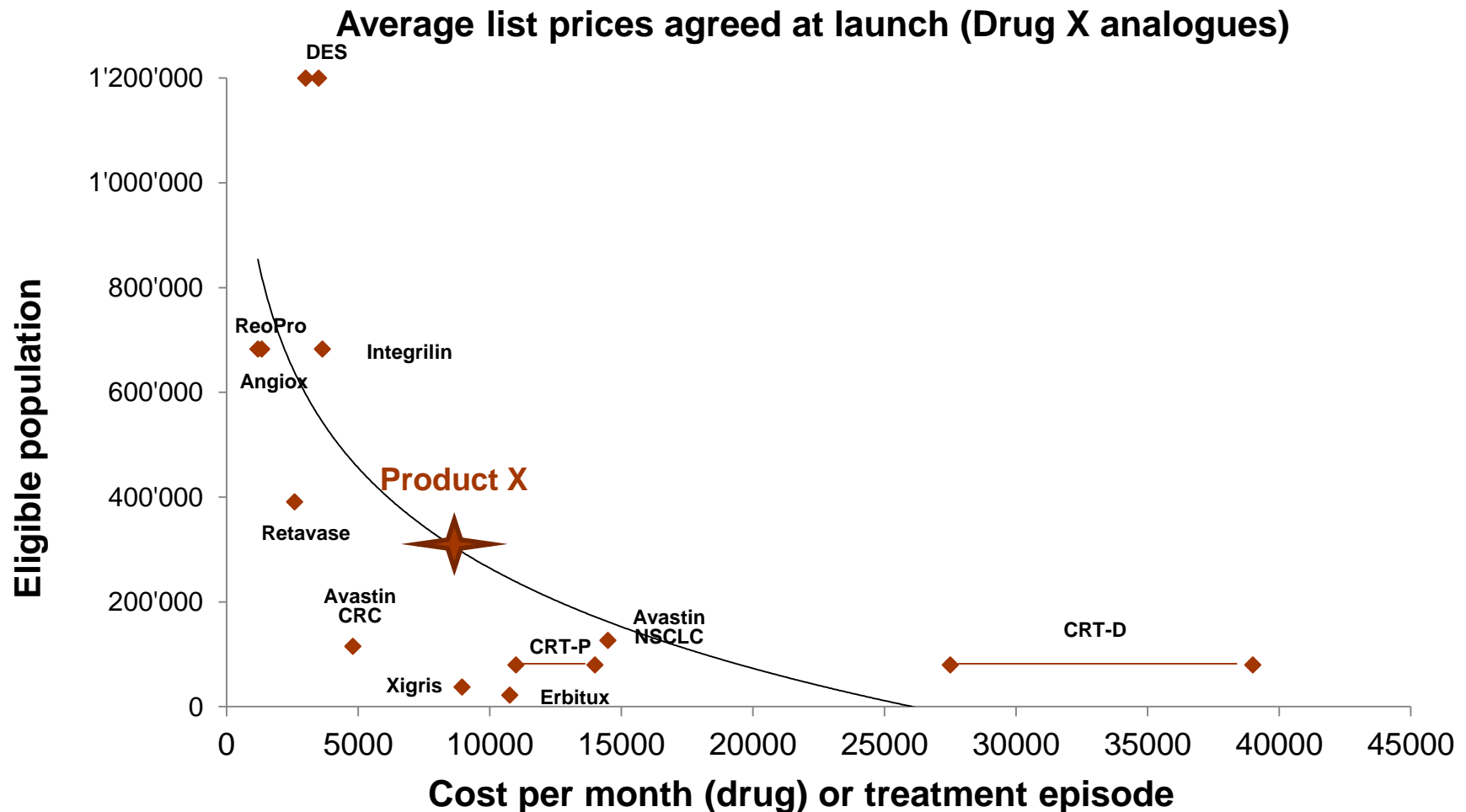
# Inform payer referencing by discuss analogues effect size



How open are you ready to be?



# Inform payer referencing by discuss analogues patient population size



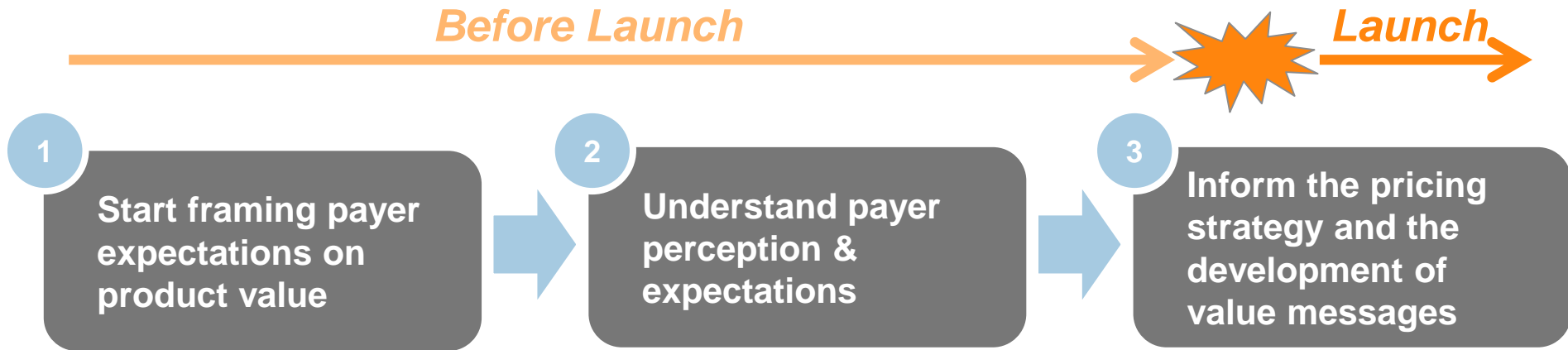
**Where do you put yourself between efficacy and population size?**

CRT-D (Cardiac Resynchronization Therapy Defibrillator) refers to all CRT-Ds analysed in the study; DES (Drug Eluting Stents) refers to all DESs analysed in the study

Source: Cowie MR et al. presented at the European Society of Cardiology 2014 congress, 30 August–3 September 2014; Poster P5878

This analysis provides the basis to engage with payers,  
frame expectations and inform the **list price**

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# Managed Entry Agreements

## MEAs are in the mouth of everybody

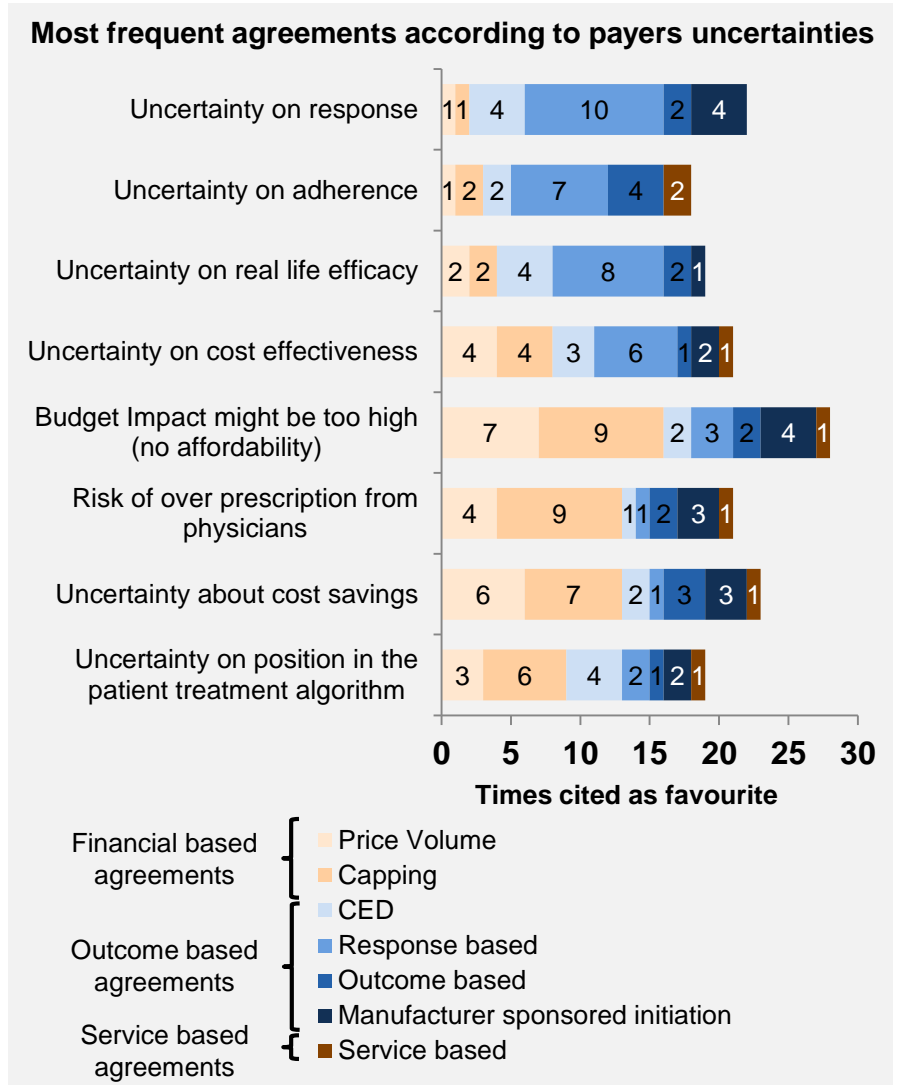
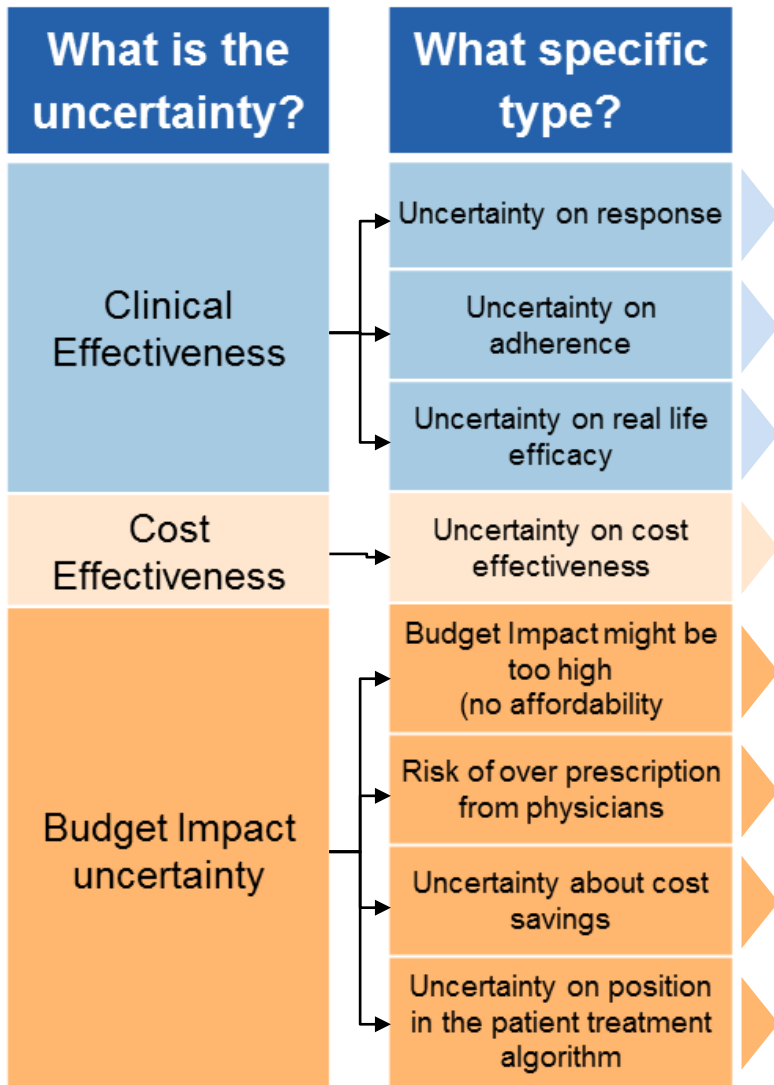
Everybody is talking about it, but very few are managing MEAs successfully

- ✓ MEAs **are not a one size fits all solution for all payers** (different level of uncertainties)
- ✓ MEAs **are not a one size fits all solution for all markets** (different preferences in each country)
- ✓ MEAs are negotiated **too late** (after negative assessment)



**How to align payer concerns with geographic preference while using right implementation approach?**

# Identify uncertainties and their relation to agreements



Questions: Do payers have any favourite agreement in your country? Cross which agreement would payers most probably choose in the following situations






# An in-depth understanding of country preferences is critical to identify applicable MEAs

Brand	# contracts // # agreements	Financial agreements				Outcome based agreements				Set up of registry for monitoring
		Rebate	PVA	Capping	Restrict.	CED	Resp.	Free init.	AEs	
Yondelis	5 // 5		PT	UK, MT	CZ	CZ	IT			IT, CZ
Prolia	4 // 3		IT		BE	BE	LT			IT, BE
Revolade	4 // 3		IT		CZ	SE, CZ				IT, CZ
Iressa	4 // 4			UK	CZ	CZ	IT, LT			IT, CZ
Lucentis	4 // 4	UK	PT			NL	IT			IT
Mabthera	4 // 2					NL (2)				IT (2)
Torisel	4 // 4		PT	BE		NL	IT			IT
Roactemra	4 // 3		IT, PT			NL				IT
Revlimid	4 // 3	IT	PT	UK						IT (2)

PVA : Price/Volume Agreement, Restrict: restrictions, CED: Coverage with Evidence Development, Resp. : Responsed-Based Agreements, Free init: Free Initiation, AEs: Adverse Events, VAA : Value Added Agreements

Source: Ferrario A, Kanavos P, Managed entry agreements for pharmaceuticals: The European experience, April 2103, London School of Economics

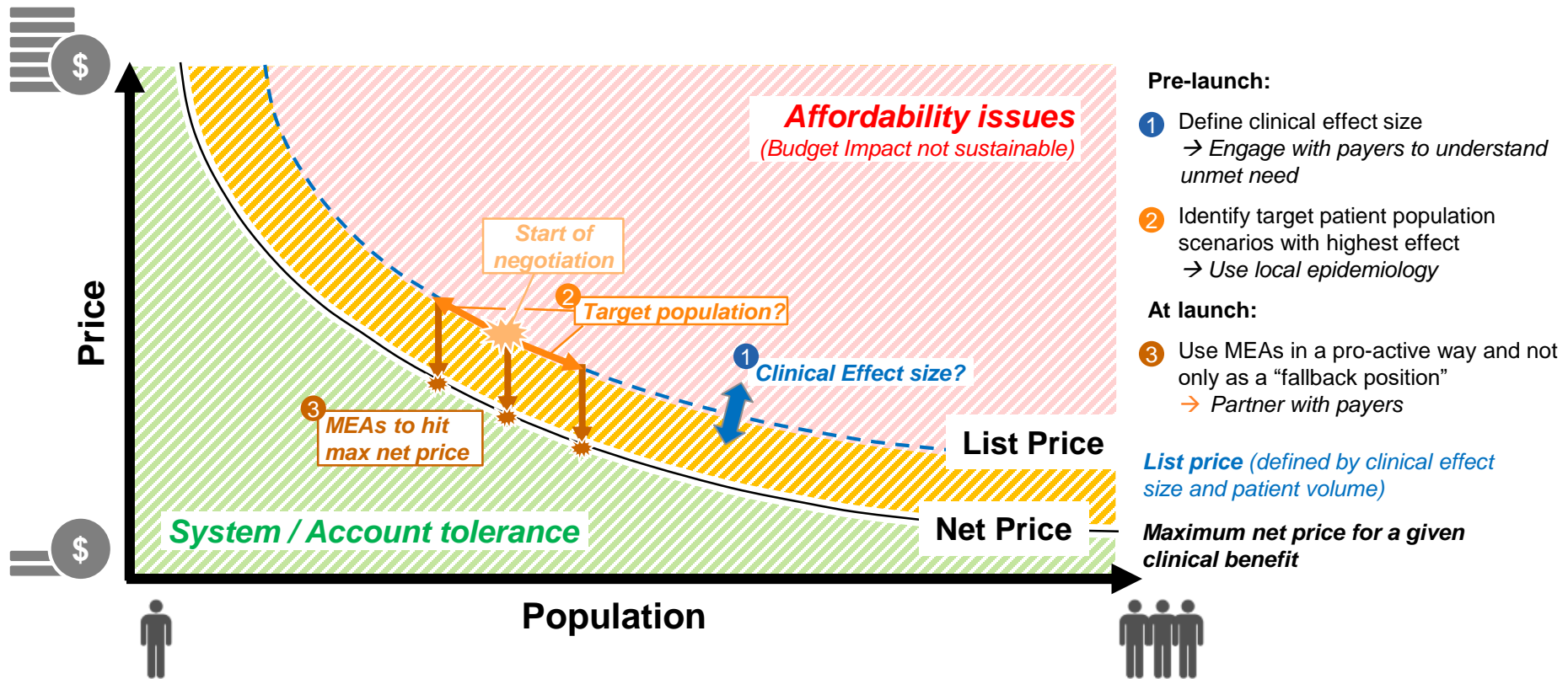
# Bring it all together with the brand perspective

What is the uncertainty?	What specific type?	In which country are you?				
						
Clinical Effectiveness	Uncertainty on response	RB	RB	RB	RB	RB
	Uncertainty on adherence	RB	RB, OB	RB, OB	RB	RB
	Uncertainty on real life efficacy	RB	OB	C, RB	RB	RB, CED
Cost Effectiveness	Uncertainty on cost effectiveness	N/A	OB	C, RB	N/A	C
Budget Impact uncertainty	Budget Impact might be too high (no affordability)	PV	PV, C	C, PV, RB	C, PV	C, OB
	Risk of over prescription from physicians	PV, C	PV, C	C	PV, VAS	C, OB
	Uncertainty about cost savings	PV	PV, OB	C	C,	PV, C
	Uncertainty on position in the patient treatment algorithm	RB	PV, C	C, CED	VAS	CED

PV: Price Volume, C: Capping, CED: Coverage with evidence development, RB: Response based; OB: Outcomes based; MSI: Manufacturer sponsored initiation, VAS: Value added service

Questions: If payers do not have a favourite agreement, what is the logic they use to decide for a specific agreement? Is there an algorithm or a decision tree?

# Clear guidance in terms of negotiation pathways clarifies options and sets boundaries for implementation

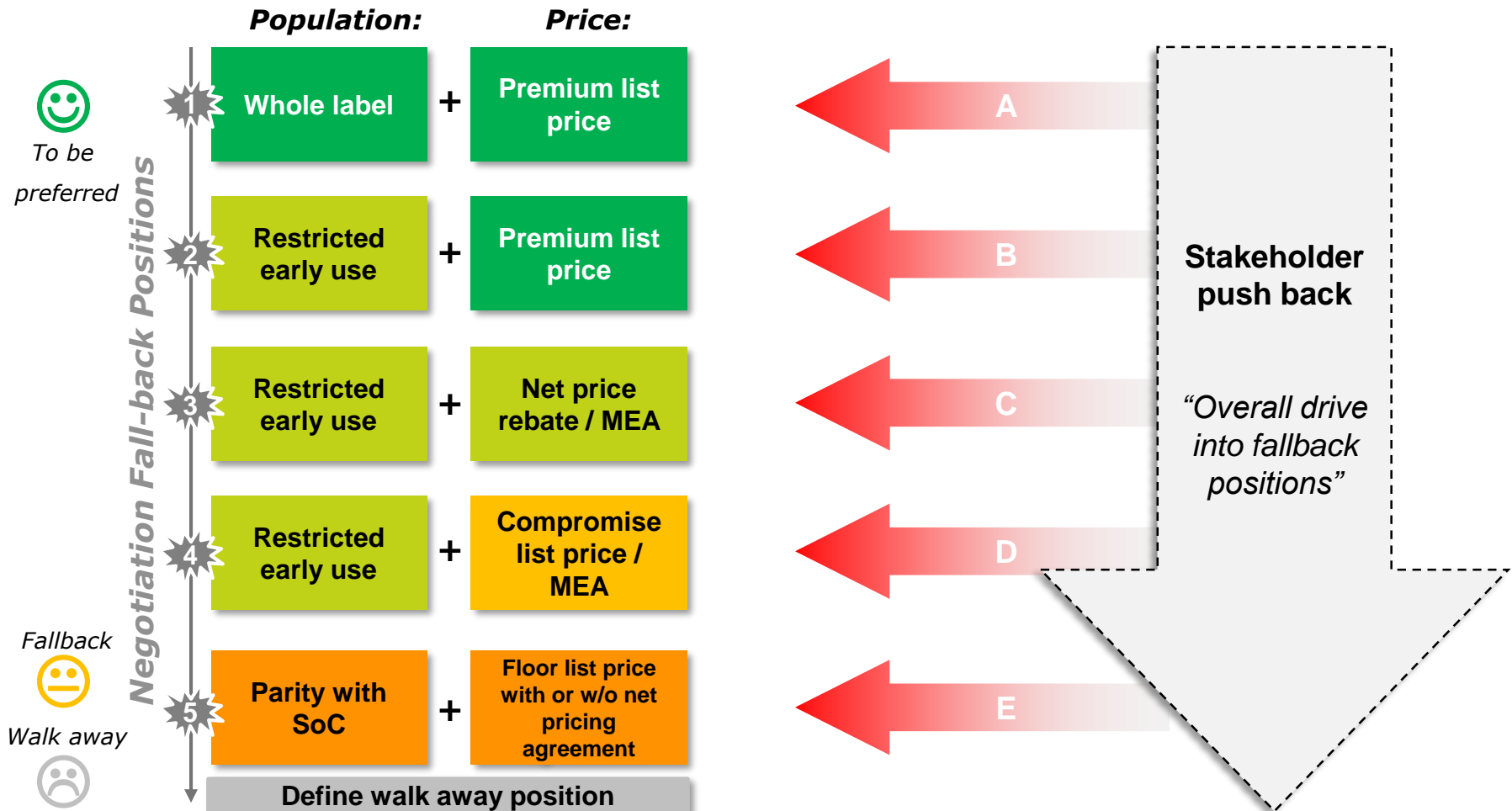


A fair negotiation considers a combination of clinical effect size, target patient volume and the system / account “ability” to absorb resulting budget impact

# A set of simple and clear negotiation options reduces the risk of sub-optimal access at national level

## Negotiation outcome (aim):

## Potential objections:





Think longer-term, be proactive, partner early and.....



...provide solid negotiation pathways for local implementation

# Let's discuss...

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