

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

Prepared for Eye for Pharma 2015

Amsterdam, June 3rd 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.**”*

Pharmafile²

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 (2015-02-27)
2: 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 Radhakrishnan¹

« 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."

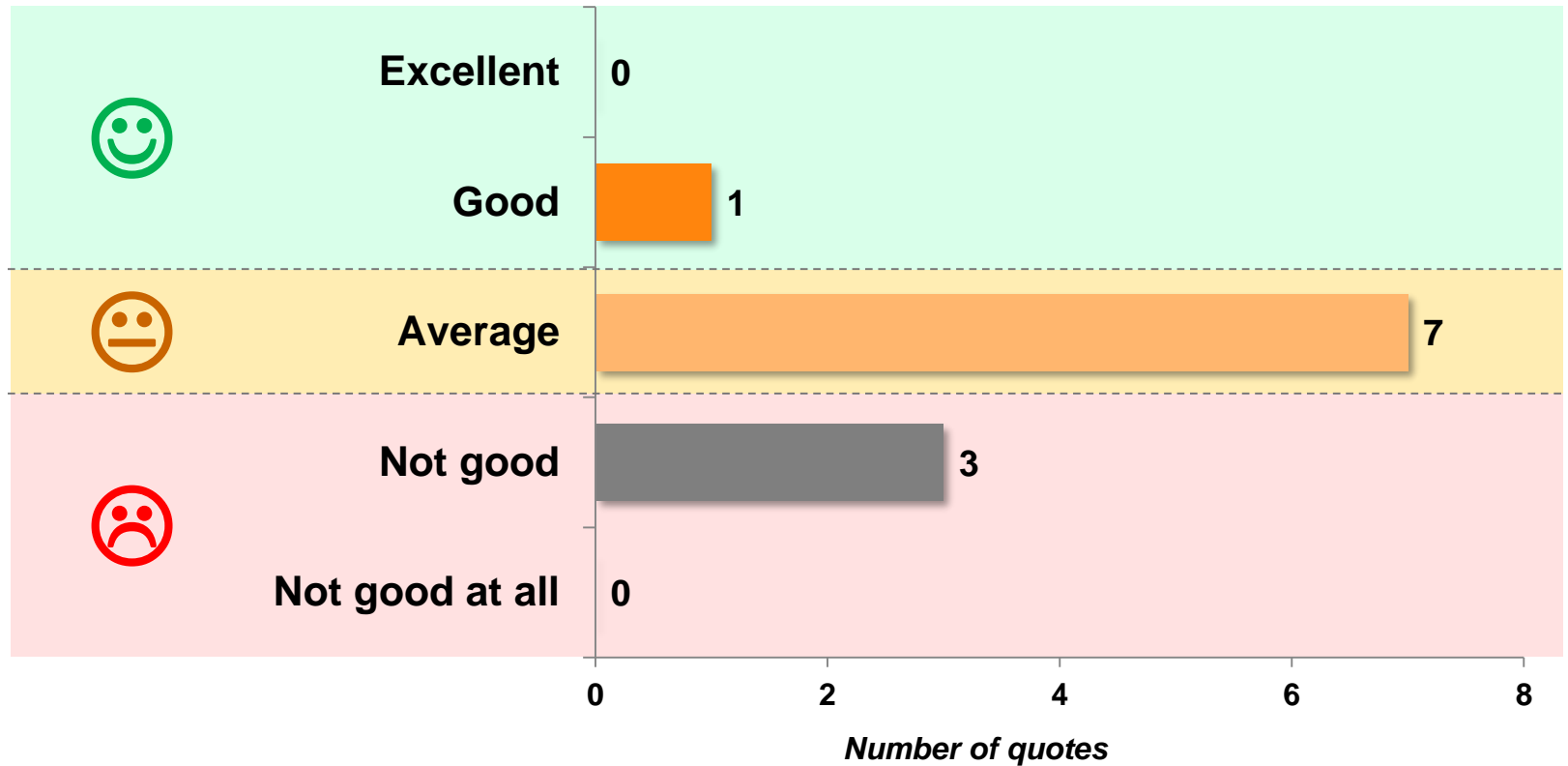
David Meeker, CEO of Sanofi's Genzyme unit²

1: www.firstwordpharma.com (2015-05-20)

2: 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?

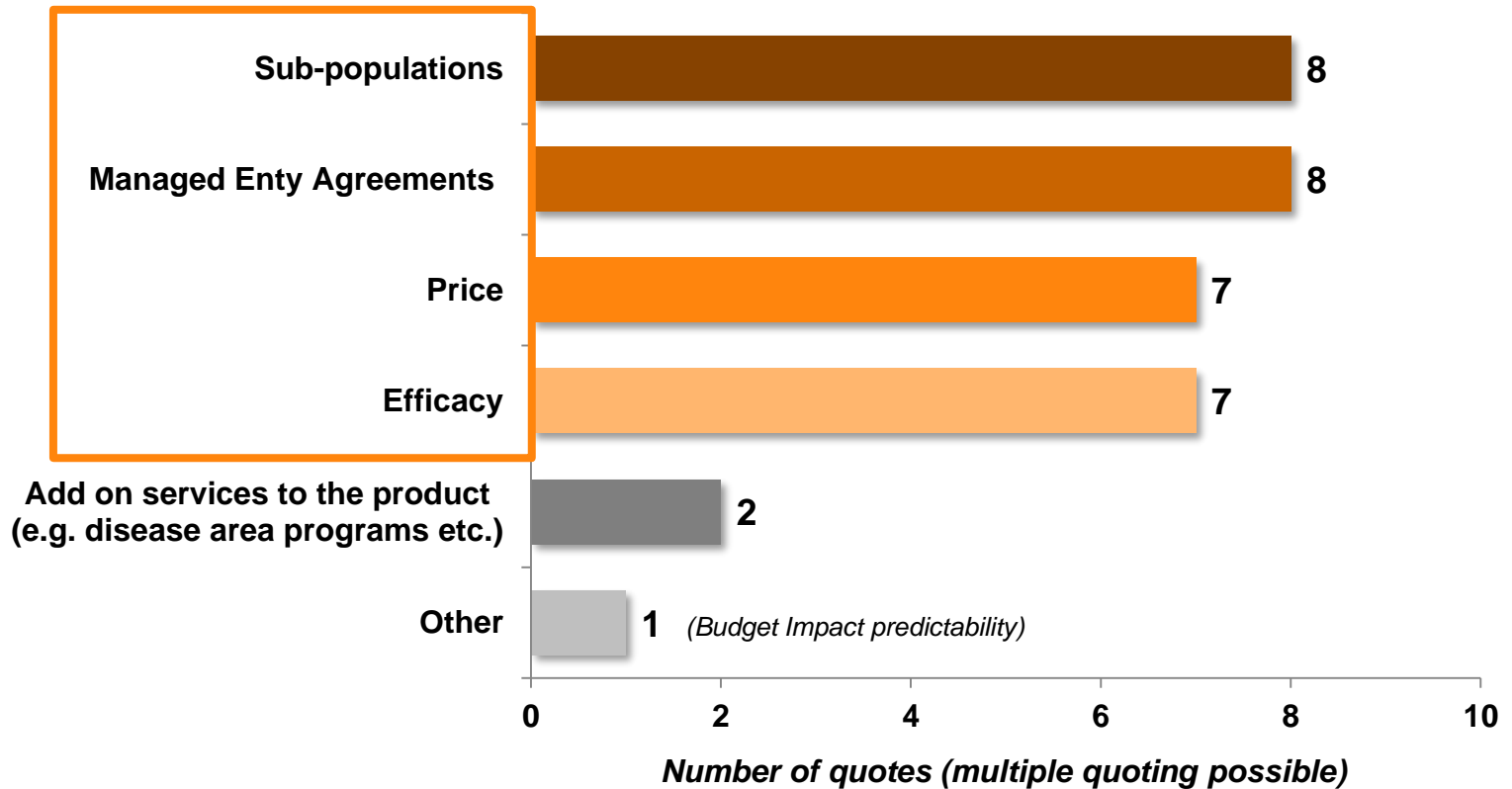


Source: Internet based survey with selected members of Executive Insight Payer Panel (n=11)

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?

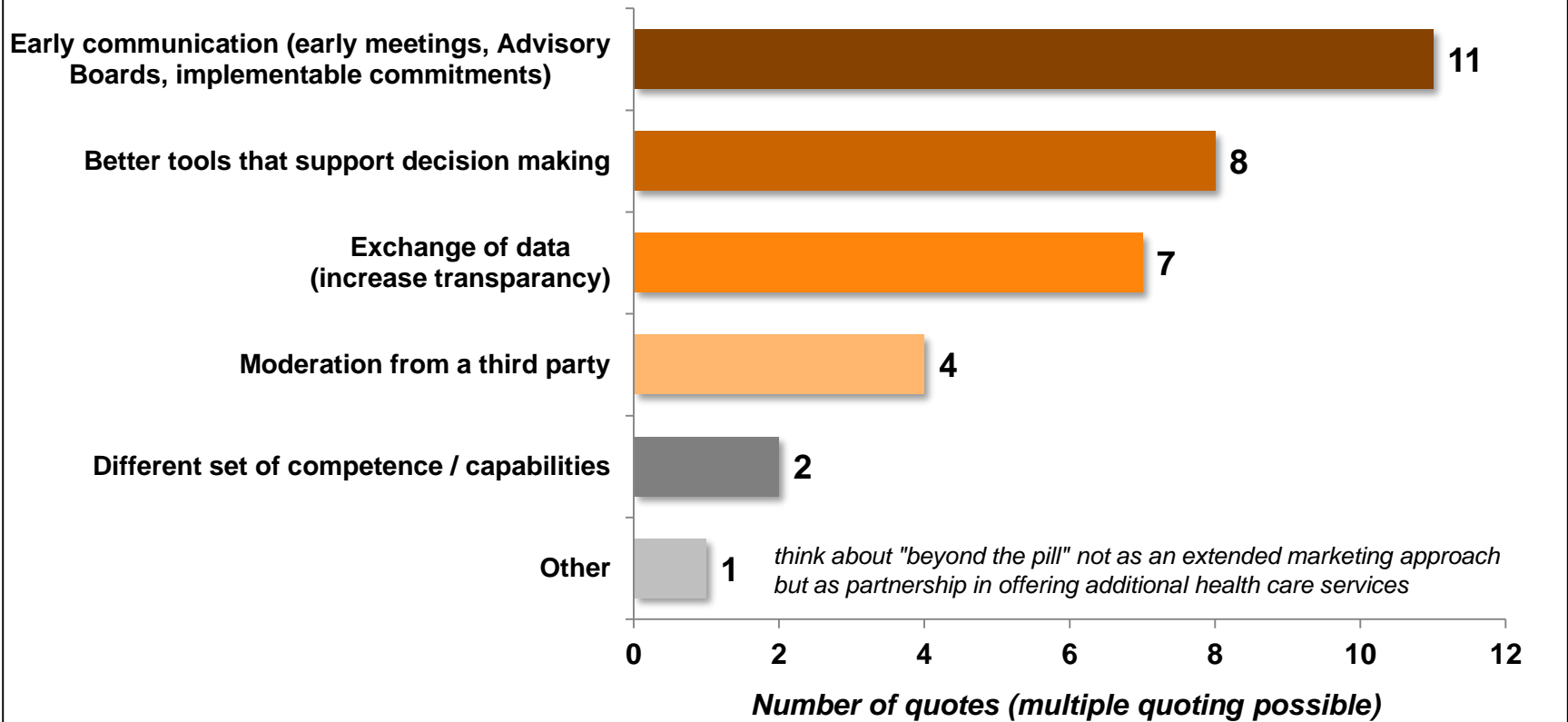


Source: Internet based survey with selected members of Executive Insight Payer Panel (n=11)

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)

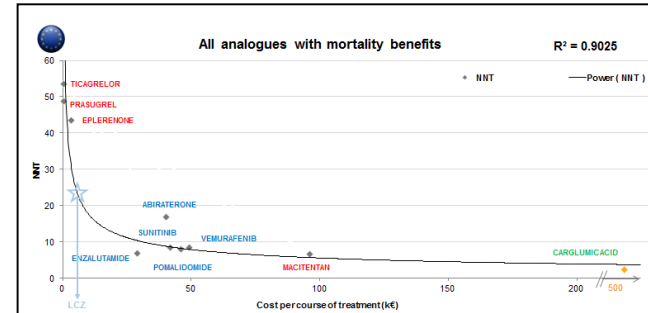
How early / proactive do we engage payers along the lifecycle?

Payer Engagement: a framework

1st Inform payer referencing

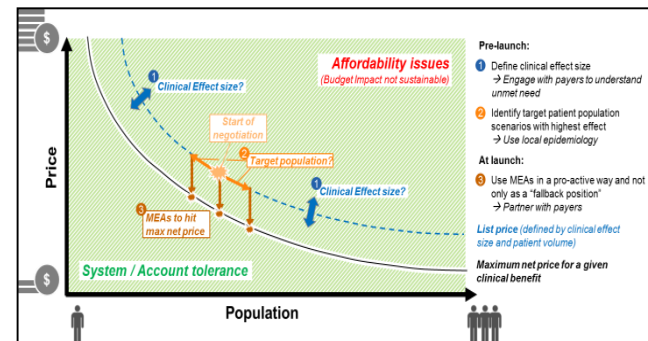
2nd Address uncertainties

3rd Maximizing value for money



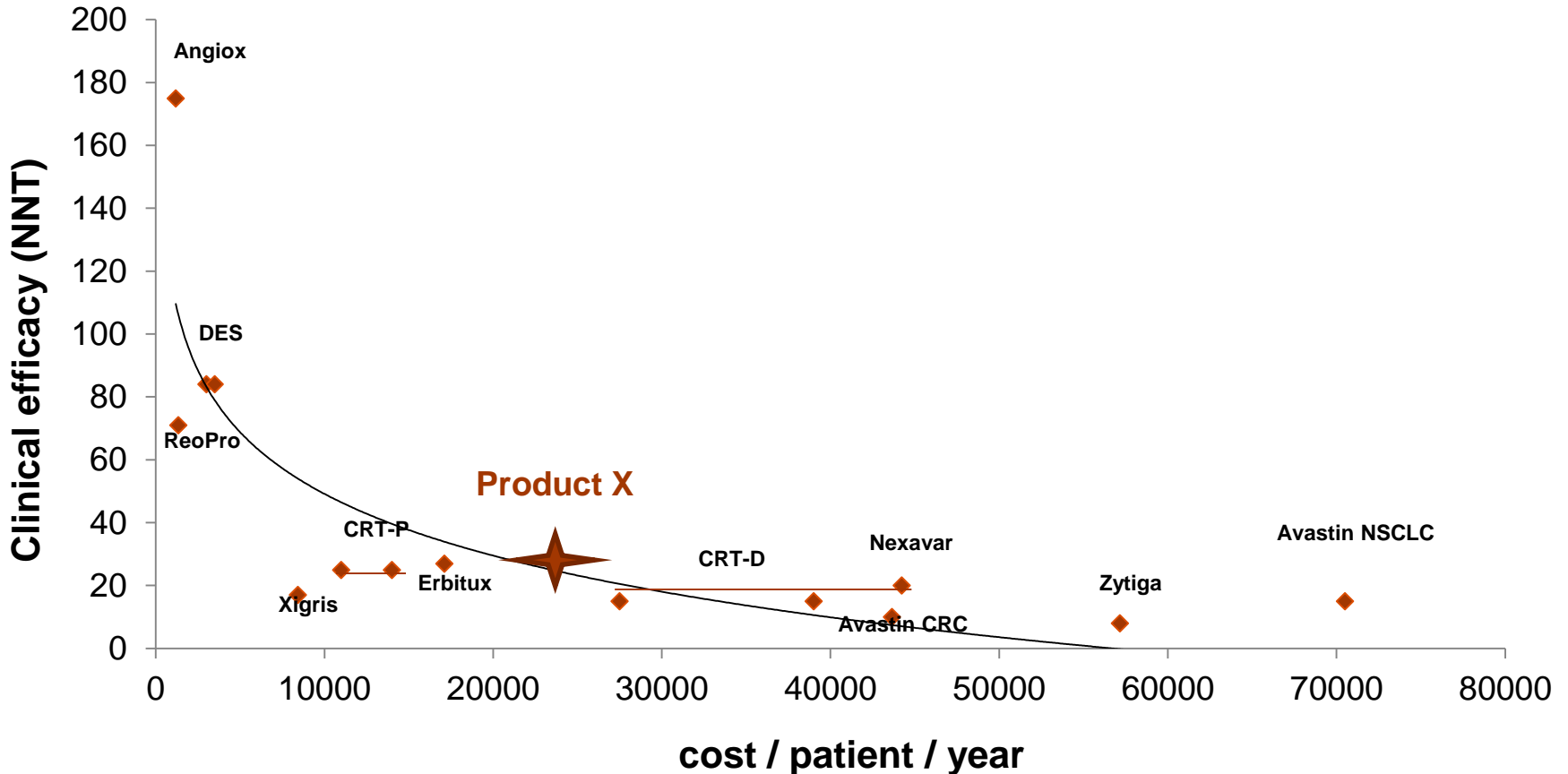
| Product X Challenges | MEAs | | Financial based schemes | | | | Performance based | | Value Added Services |
|--|----------------------|-----|-------------------------|--------------------|----------------------|-----------------|--------------------------|-----------------------------------|----------------------|
| | Undiscounted rebates | PVA | Cap per patient | Population capping | Portfolio Trade-Offs | Free initiation | Rebate on non-responders | Outcome Achievement based pricing | |
| Physician use in 1 st line | X | ● | | X | X | X | | | |
| Uncertainty on Budget Impact | | ● | | | X | | | | |
| Use in overlapping patient group | | ● | | | X | X | | | X |
| Uncertainty of the superior efficacy | | | X | | | | X | | |
| Believe that competitor is more cost-effective / cost-saving | | | | | ● | | X | X | |
| Uncertainty that cost-savings are possible in the long term | | | | | | | | X | |
| Most expensive drug | ● | X | X | X | X | | | | |
| The disease is a key focus of cost containment | | | | | | | | | ● |

Legend: ● First option to be considered, X Potentially useful, X Implemented/requested but not recommended



Inform payer referencing by discuss analogues effect size

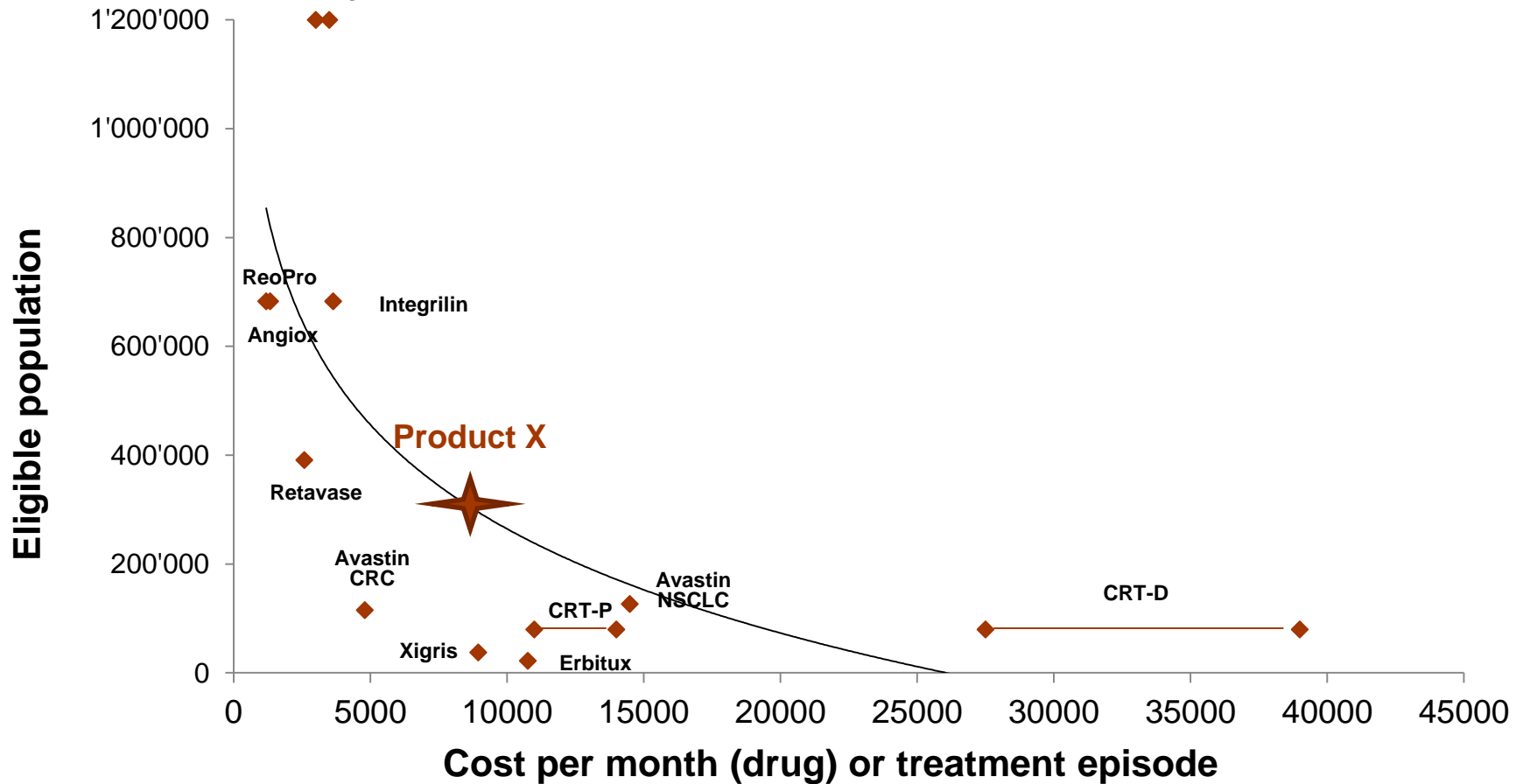
Average list prices agreed at launch (Drug X vs. analogues)



How open are you ready to be?

Inform payer referencing by discuss analogues patient population size

Average list prices agreed at launch (Drug X analogues)

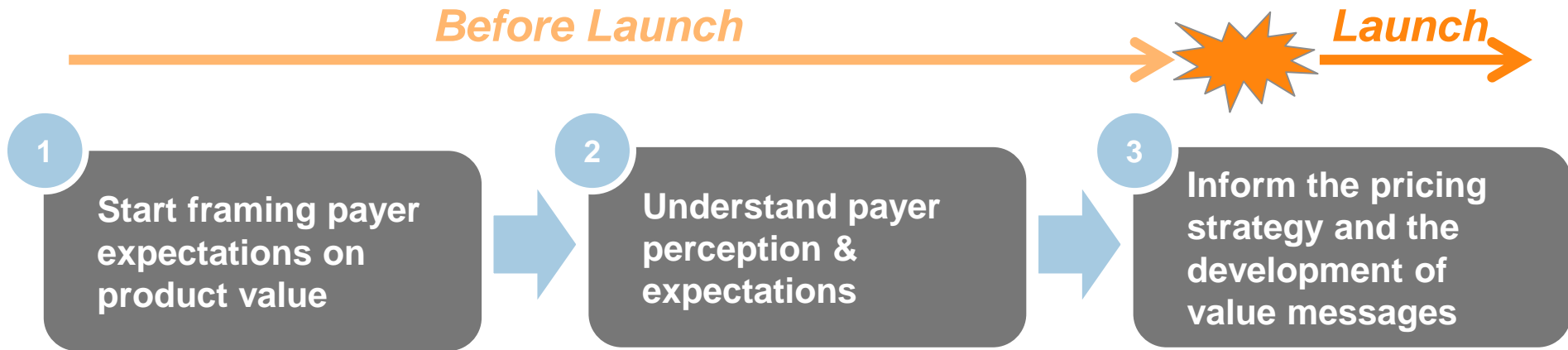


Where do you put yourself between efficacy and population size?

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**



Managed Entry Agreements

MEAs are in the mouth of everybody

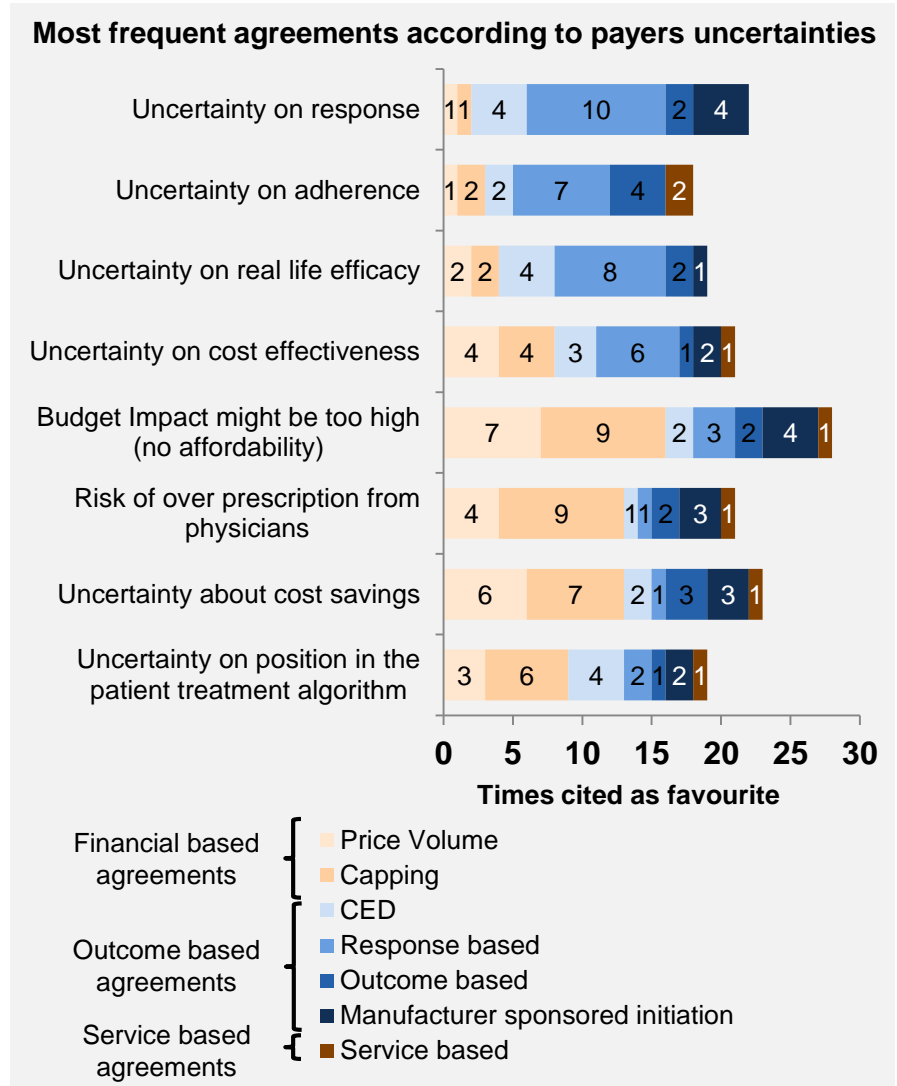
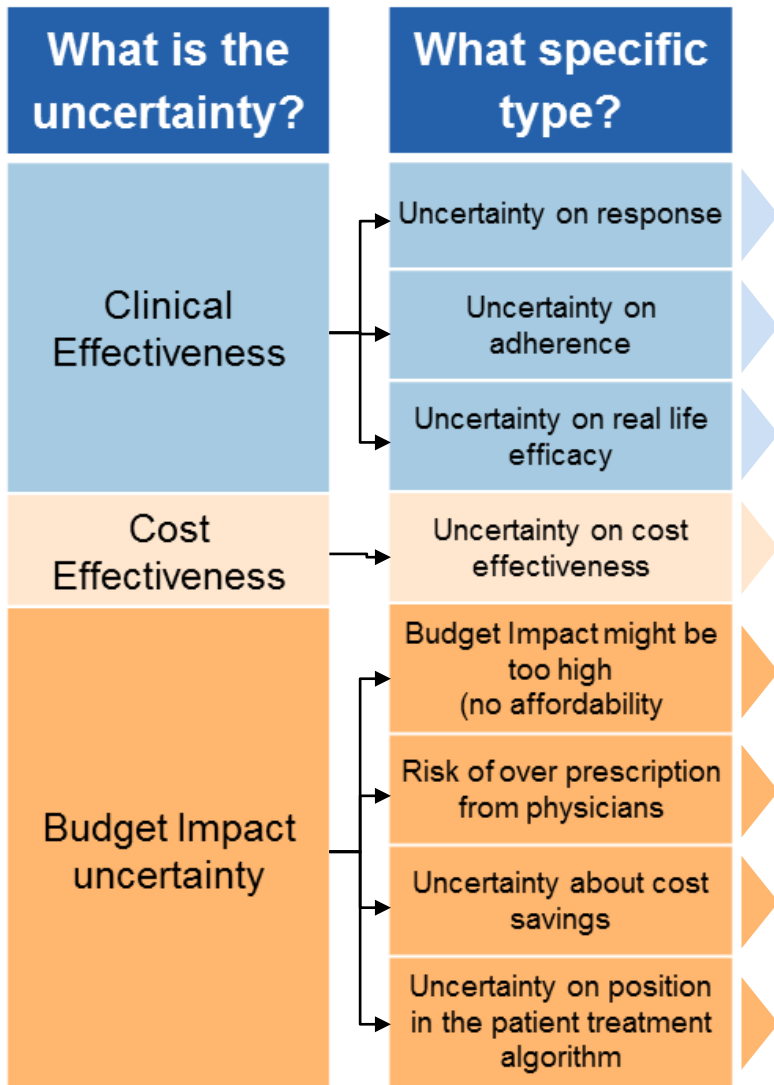
Everybody is talking about it, but very few are managing MEAs successfully

- ✓ 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. : Responder-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

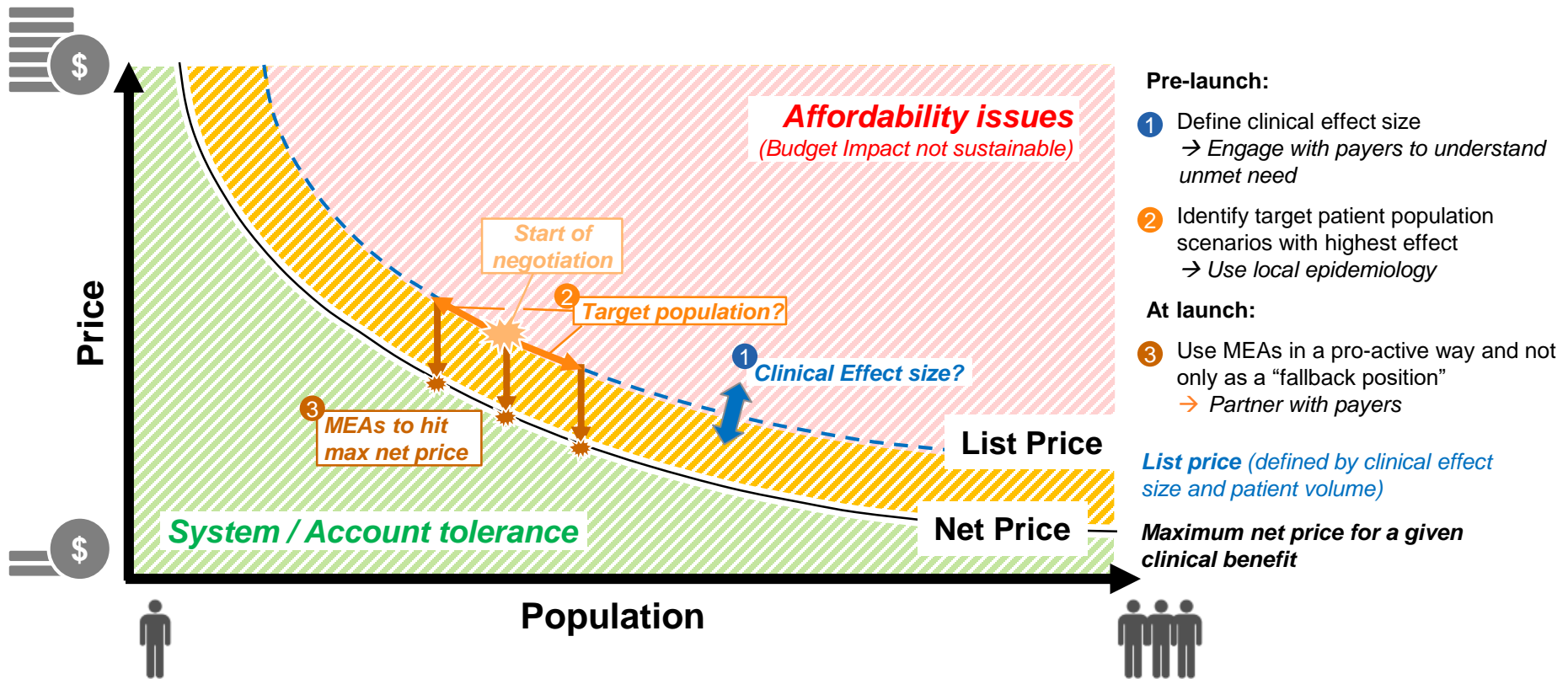
Bring it all together with the brand perspective

| 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

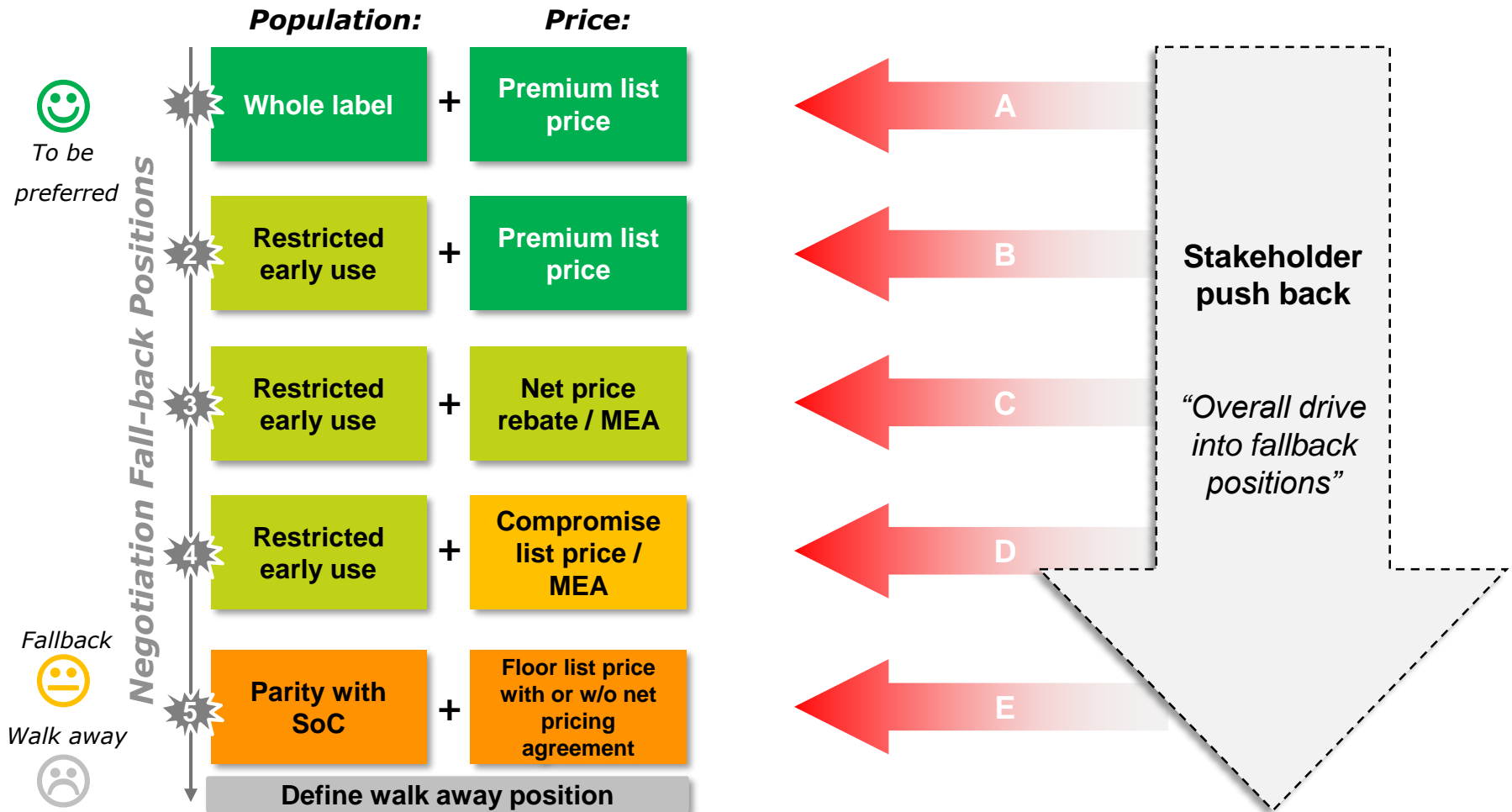


A fair negotiation considers a combination of clinical effect size, target patient volume and the system / account “ability” to absorb resulting budget impact

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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