Industry Perspective

Diego Guarin MD MPH MA
Senior Director HEOR & HTA Strategy Merck KGaA
ISPOR Health Science Policy Council & LA Consortium
FIFARMA Healthcare Sustainability Working Group

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"Not paying for a drug unless it works sounds great for patients and healthcare funders, but it could also benefit manufacturers"

- On one side, the authorities have fewer financial resources at their disposal relative to the many drug options available and the increasing need for treatment caused by a swell in the ageing population.

  Fewer resources naturally lead to increased focus on how money should be spent and what the return is in practice.

- On the other side, drug companies have had to become more competitive as a result of the falling number of new chemical entities, "me too" strategies, generic production, and parallel imports. Mergers of major drug companies have also increased competitiveness.

Source: Møldrup C. No cure, no pay. BMJ (2005)

Box 2: No cure, no pay strategies

1994: Merck-Frost offered refunds to patients who had been prescribed finasteride if they required surgery for benign prostatic hyperplasia after one year of treatment.[6]
1995: Sandoz introduced a money back guarantee for clozapine for treatment resistant schizophrenia. The reimbursement covered the costs of the drug, dispensing fees, and pharmacy mark-ups.[7]
1998: Merck promised to refund patients and insurers up to six months of their prescription costs if simvastatin plus diet did not help them lower LDL cholesterol to target concentrations identified by their doctors.[8] The guarantee still applies.[9]
2004: Novartis launched a no cure, no pay initiative for valsartan and valsartan hydrochlorothiazide as part of a "take action for healthy blood pressure" programme in the United States.[10] In addition to a money back guarantee for the patient only, the programme also provides the option of a 30-day trial product package, the opportunity to buy a blood pressure measuring device cheaply, and various on-line compliance systems.
2004: Novartis launched a no cure, no pay initiative for valsartan in Denmark, independent of the initiative in the US[11].
2004: Lilly ICOS launched a no cure, no pay on tadalafil for erectile dysfunction in the US. Patients who were not satisfied with the treatment were issued with a voucher for the oral treatment of their choice[12].
2005: Novartis launched a money back initiative in Denmark for nicotine chewing gum. If the patient does not like the taste (four tastes to chose from), a refund is offered.
2005: Bayer launched a no cure, no pay initiative on vardenafil for erectile dysfunction in Denmark. Patients who are not satisfied with the treatment can get the cost refunded.[13]

BMJ VOLUME 330 28 MAY 2005 bmj.com

EMA - Medicines Adaptive Pathways to Patients (MAPPs)

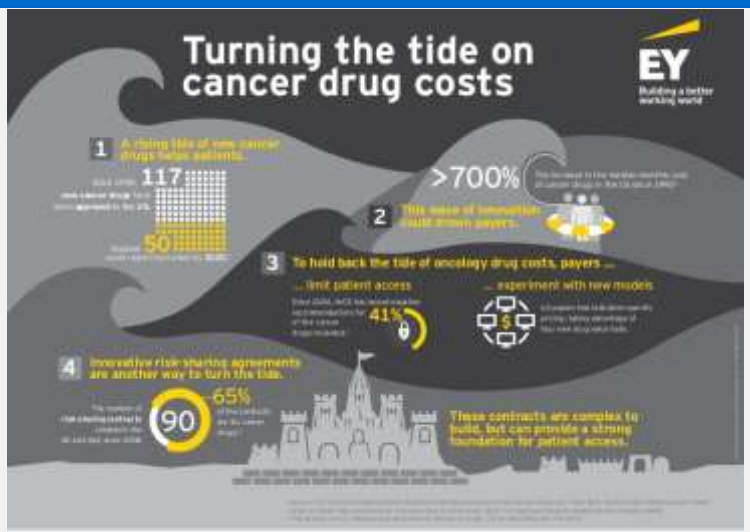
So why is this strategy not more widespread? The answer is simple, there has been no need!

- Price is main relevant attribute
- Value of innovation is uncertain
- Short-term "savings"
- *The difficult we do immediately…*

- Value attributes are most relevant
- Value of innovation is proven
- Long-term savings
- *The impossible just takes a little longer*

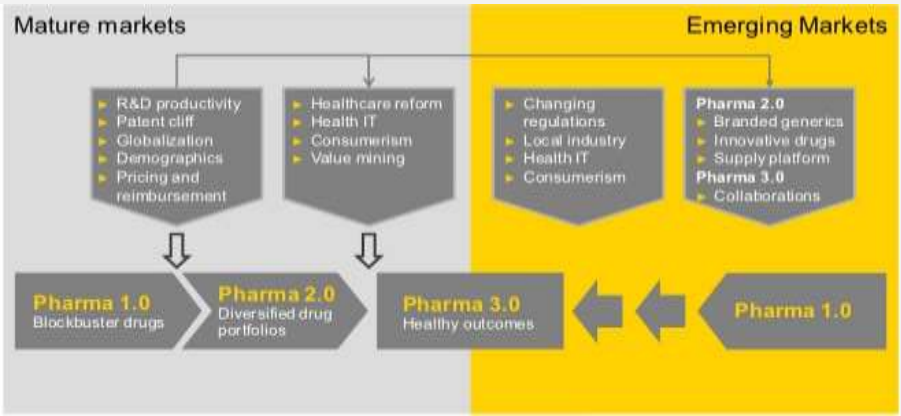
Source: Frenoy E. EFPIA - HTA and managed entry practices in Europe - Pharmaceutical industry perspective (2011)

Yet, as the rising tide of new treatments is drowning payers, industry's creative juices are flowing…



Source: Ernst & Young. The Economist's War on Cancer (2015)

Evolution of thinking
Pharma 3.0 from marketing drugs to outcomes



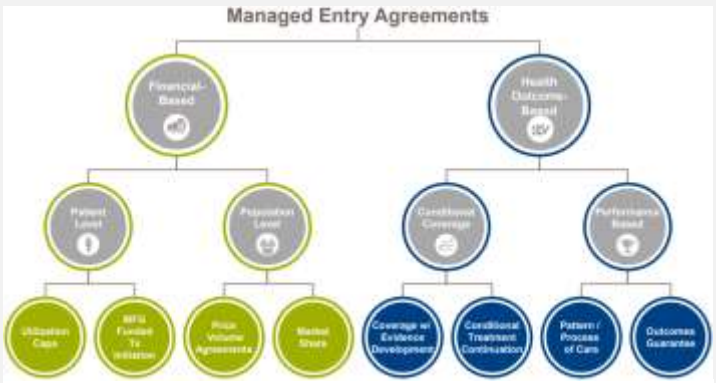
Source: Ernst & Young. Pharma 3.0 (2011)

MEA what does it mean?

*"An arrangement between a manufacturer and payer/provider that **enables access** to (coverage/reimbursement of) a health technology **subject to specified conditions**. These arrangements can use a variety of mechanisms to **address uncertainty** about the **performance** of technologies or to manage the **adoption** of technologies in order to **maximize their effective use**, or **limit their budget impact**" from HTAi Policy Forum 2010.*

Key sources of uncertainty:

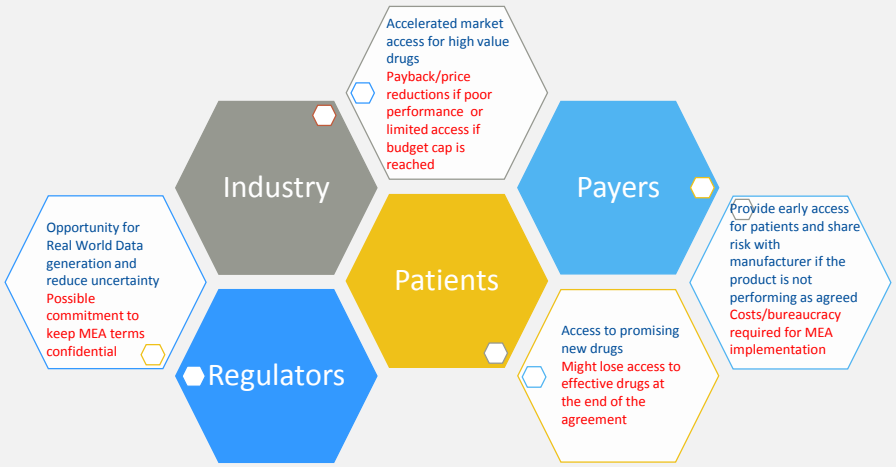
- Around clinical evidence
- Around eligible patient population
- Around cost-effectiveness
- Around budget impact
- Around price



Garrison L. et al. ISPOR Good Practices for PBRSA Task Force. Value in Health (2013)

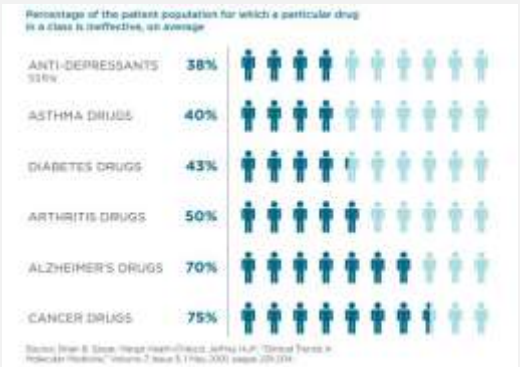
Source: Klemp M. et al. What principles should govern the use of managed entry agreements? Int J Technol Assess Health Care (2011)

MEA: Abridged Pros and Cons

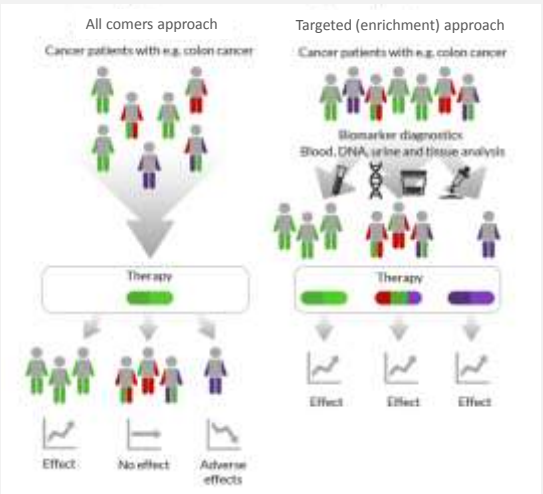


Source: Klemp M. et al. What principles should govern the use of managed entry agreements? Int J Technol Assess Health Care (2011)

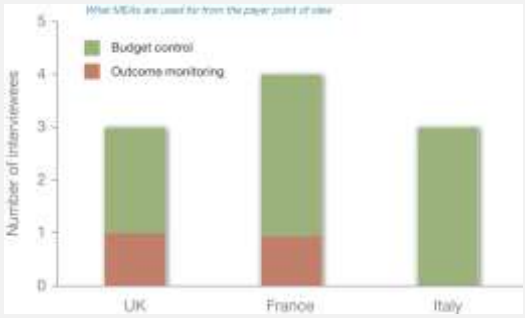
The problem (1)
"One drug does not suit all"



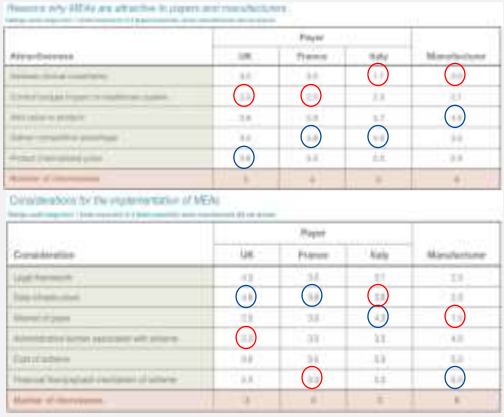
Studies have linked differences in response to the differences in genes that code for the drug metabolizing enzymes, drug transporters, or drug targets.
For instance, a MEA based in biomarkers allows the physician to select an optimal therapy the first time and to avoid the frustrating and costly practice of trial-and-error to the payer.



The problem (2)
Payer and Industry drivers and barriers differ*



Industry responders perceived MEAs as an approach to **accelerate market access** for **premium-priced drugs**
Although a **confidential straight discount** was **preferred**, addressing the **uncertainty** about **clinical benefits** via outcome-based approaches was of particular **interest** in oncology
Payer stakeholders said MEAs were currently used mainly as instruments to **reduce the drug's budget impact**



Both payers and industry respondents thought that an MEA should be **transparent** and **simple**, and address the specific incentives of the various stakeholders in the healthcare system

Source: Lucas F., Wong I. Payer vs. Industry views on Managed Entry Agreements. Value in Health (2015) *(Survey of 9 companies and 10 payers)

The problem (3)
Only few countries are paving the way*

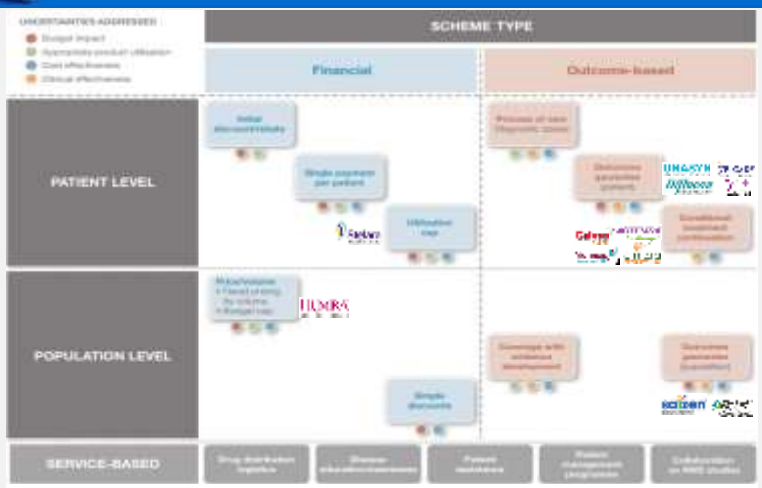
Most countries have **limited** examples of **outcomes based MEAs** adopted in the past, with the exception of Australia and Italy.
Yet, 2/3 expressed greater interest in negotiating them for **selected high-budget impact products** with Colombia expressing interest in adopting them more broadly.

Drivers in outcomes based MEAs include: **uncertainty over benefits** of new therapy, and especially in Colombia, the difficulty in controlling **budget impact** through other mechanisms
Key **challenges** for adoption include: difficulty in accurately **measuring outcomes**, lack of **logistical capabilities**, rigidity of **current framework** and difficulty incorporating **new processes**

Source: Xue Y. et al. Adoption of MEAs in Established and Emerging Markets. Value Health (2016) *(Interviews of 5 payers per country)

MEAs in Latin America
Are we catching-up…

…or still lagging behind
few, short lived, confidential examples



Adapted from Lucas F., Wong I. Payer vs. Industry views on Managed Entry Agreements. Value in Health (2015)

Source: Garrison L., Guarin D., Sullivan S. Xuan J. Risk-sharing schemes in emerging countries: What are the steps for success?. ISPOR 3rd LA Conference(2011)

Managed Entry Agreements in LATAM Industry Perspective (my take)

- Only few “true” agreements performed in LATAM
  - Many are masked discounts (e.g. rebates, free goods, portfolio deals)
  - Few, short lived examples, most remain confidential
  - Health system fragmentation, poor IT capabilities and lack of a legal framework among key barriers
- MEAs have been usually offered for premium price drugs, or for smaller patient populations or in niche therapy areas
  - Majority are financial based: utilization or budget caps
  - Outcomes based patient-level examples have had handy and easy to measure outcomes (≤12 weeks)
  - Outcomes based population-level proposals have not get traction yet
- MEAs in the region have had a limited reach (e.g. by geography, payer segment and therapeutic area) with apparently marginal results in both sides of the table
- Future success depends on the willingness from payers to engage in an agreement beyond the customary straight discounts or (tier-)price/volume agreements