White Paper

Medicines pricing using a trading platform

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Contents

Dr Mike Tremblay has a doctorate from the University of Toronto, combining public policy and psychology. He has over 25 years of experience with life sciences/healthcare business strategy, applying quantitative and analytical methods to payer, and medical decision making. Understanding how healthcare and life science systems around the world work informs his work on market access, pricing and reimbursement, clinical decision-making and patient treatment. He is a director of Cassis Limited and holds a research appointment at the University of Kent.

1 What is the problem?

Governments have tried just about everything to regulate or control medicines pricing but have not tried a transparent, regulated trading approach.

1. Research and innovation in the pharmaceutical industry is producing medicines that benefit smaller populations, with higher costs, presenting countries with significant affordability problems.
2. Current pricing models do not necessary translate into best prices arising from opaque pricing agreements, which often hide true (discount) pricing behind commercial-in-confidence agreements. Reference pricing, for instance, depends on true pricing, but list prices dominate reference baskets, artificially inflating the price of a medicine.
3. Tendering for generic medicines, with winner-take-all results, leads to limited future supply availability and puts purchasers and payers at risk of suppliers who exploit monopoly pricing power.
4. Payers have no mechanism for 'forward pricing' or hedging for the future price of novel medicines in early (Phase 2) discussion with pharmaceutical companies but must wait until Phase 3 and product launch before the pharmaceutical company announces the 'launch price' for a novel medicine, at which time the payer, as a price taker, now must negotiate down to an affordable price for them.

2 Why a trading platform might be used to price medicines

The opportunity arises from a constellation of factors that exist in every OECD country and all lower and middle income countries.

2.1 What keeps Ministers of Finance and Ministers of Health awake at night?

- Current healthcare costs are deemed unsustainable against anticipated levels of supply, demand and available funding;
- Cost-sharing and taxation are approaching the level at which the public will no longer support increased demands on disposable income;
- Social security insurers are under increased scrutiny from weak control healthcare costs, and weak encouragement of improved productivity and

value for money by providers.

2.2 What are the drivers of change in the healthcare ecosystem?

- The public expects personalised, on-demand care, expectations for which is rising and prompting healthcare providers to change service delivery and explore new models of care delivery, driving new expenditure models.
- Precision medicine and the dominant paradigm in the life sciences research community is moving from blockbuster drugs to medicines that target specific diseases in smaller populations defined with precision using biomarkers, such as genetic markers from genomic/exomic sequencing;
- Healthcare data in electronic health records can be used to better match the clinical demands of specific patient populations with targeted supply of medicines and services, replacing the pharmaceutical industry's traditional 'selling' model with precision prescribing and medicines procurement;
- Medicines regulators are adopting the analytical techniques (cost-utility analysis, multi-criteria decision analysis etc.) used in the assessment of medicines and devices ('health technology assessment') to inform decision making on the approval, adoption and reimbursement of medicines, moving beyond their traditional role focused simply on medicines licensing; they are also increasingly exploiting their monopsony purchasing power.

2.3 How does medicines supply, pricing, and procurement work?

The medicines supply chain is one of the most of the most complex in the world, spanning all countries, with a combination of manufacturers, distributors, wholesalers, and other various intermediaries through to dispensing of those medicines by doctors, pharmacists and hospitals;

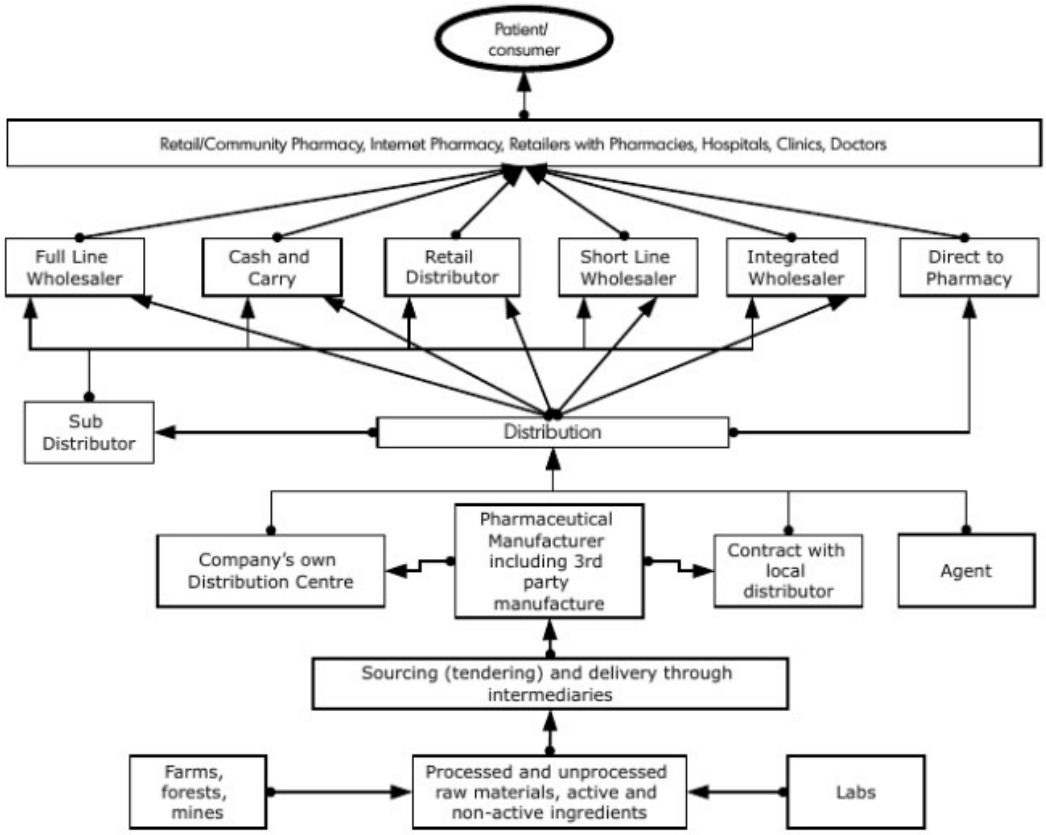


Fig. (2). Overview of the complex supply chain [diagram by the author].

Figure 1: Medicines supply chain Source: Tremblay

Medicines including vaccines are complex and carry huge risks, with some medicines required to be transported in an unbroken cold-chain, and others at risk of criminal diversion to the black market and counterfeiting by organised crime;

Many medicines are highly specialised and carry very high prices reflecting both small treatment populations such as for rare diseases and complex manufacture, such as Soliris [eculizumab], a humanised monoclonal antibody which is used to treat paroxysmal nocturnal haemoglobinuria, a rare life-threatening disease of the blood and which costs in excess of US$400,000 per patient per year;

Medicines pricing is a complex negotiation of initial price-setting by pharmaceutical manufacturers and reimbursement approval based on health technology assessment and comparative international pricing ('reference pricing') by national regulatory pricing authorities, with very few countries permitting unregulated pricing ('free

pricing') of prescription-only medicines;

For new prescription-only medicines, manufacturers hold intellectual property protections that provide a temporary monopoly on selling the product in the countries in which they have received regulatory approval to sell that medicine ('marketing authorisation'), and which confers a temporary right to try to achieve 'monopoly pricing', subject to pricing and reimbursement agreement with public authorities.

Pharmaceutical companies price their medicines according to what the market ('payers') is prepared to afford to pay, which produces a 'pricing corridor' bounded broadly by the company perception of payer affordability/unaffordability for that medicine and between which they arrive at an agreed price; complicating this price negotiation is the impact of health technology assessment which may rate affordable medicines as uneconomic based on cost-utility analysis, for instance, and thereby failing on value for money (called the 'fourth hurdle'), in which case the pharmaceutical company may choose not to offer that product to that market, negotiate a managed entry agreement ('market access scheme', 'patient access scheme') or simply discount the medicine to the point at which it passes the economic tests.

Generic medicines are medicines that are no longer protected by the originator's patents, and are therefore able to be manufactured at lower costs by generic drug companies who often brand their generics (ibuprofen, invented by Boots in the UK, is the generic medicine while Nurofen, Advil are the branded generic), with such medicines frequently not price controlled by regulators (there are significant country exceptions);

Generics are often bulk procured by public authorities for their pharmacies through single-source tendering so that when tenders are awarded, the winner gets the whole of the country's market for that drug ('winner takes all'), which leads to risks of shortages when the sole supplier cannot meet demand ('stock-outs') and leads to smaller competing companies exiting that market, reducing supply competition for future tenders and thereby complicating market entry for new suppliers and reducing market contestability;

A substantial segment of a country's medicines will be composed of generics and account for as high as 75-80% of all prescriptions filled, while a wide range of generics do not require a prescription and can be bought directly by consumers ('over the counter' or OTC).

The willingness of payers to pay prices (public payer 'affordability') has many determinants as does the willingness of the manufacturer to place a specific medicine into a market (pricing and margin policy, coupled with the importance of the market to the company); together, these determine availability of a specific medicine in a specific country.

2.4 How would a trading platform work?

The diagram summarises the basic logic of the trading platform. It operates little differently from any other approach that is used around the world.

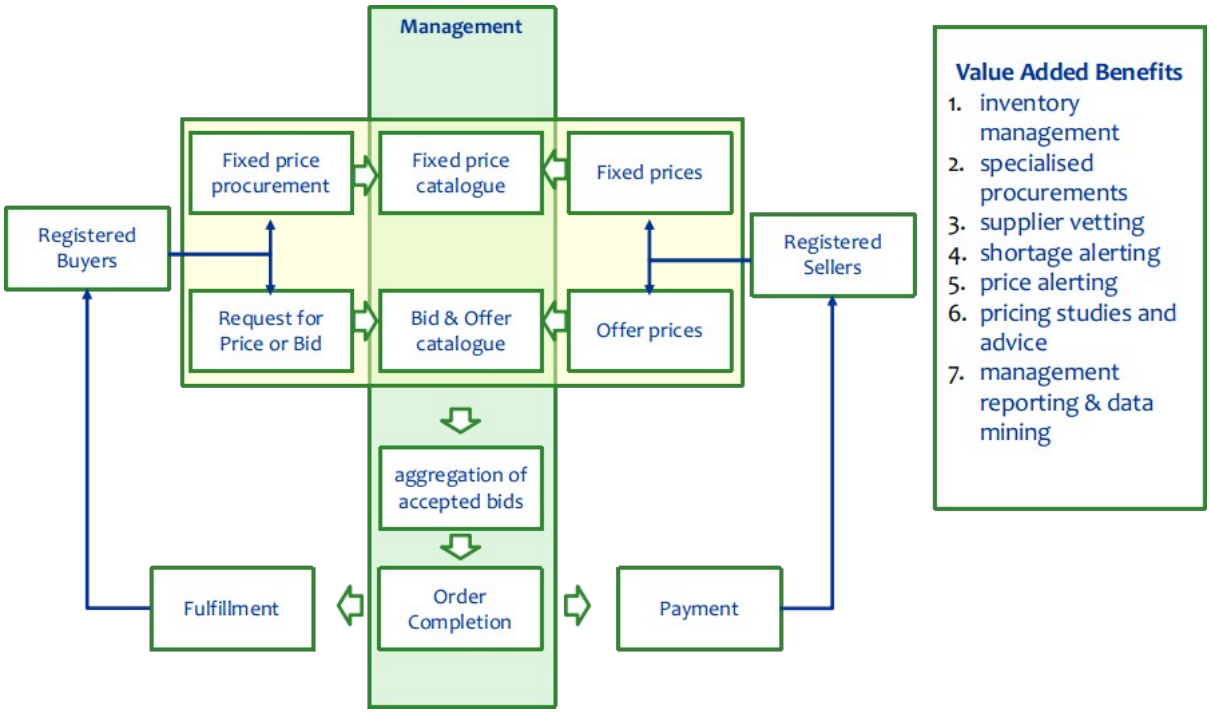


Figure 2: Simple trading schematic Source: Tremblay

2.5 Strategy canvas: trading platform versus standard tendering

Using Blue Ocean strategic canvas, this approach out performs tendering, the dominant current form of procurement and pricing; these features similary apply to any system of negotiation.

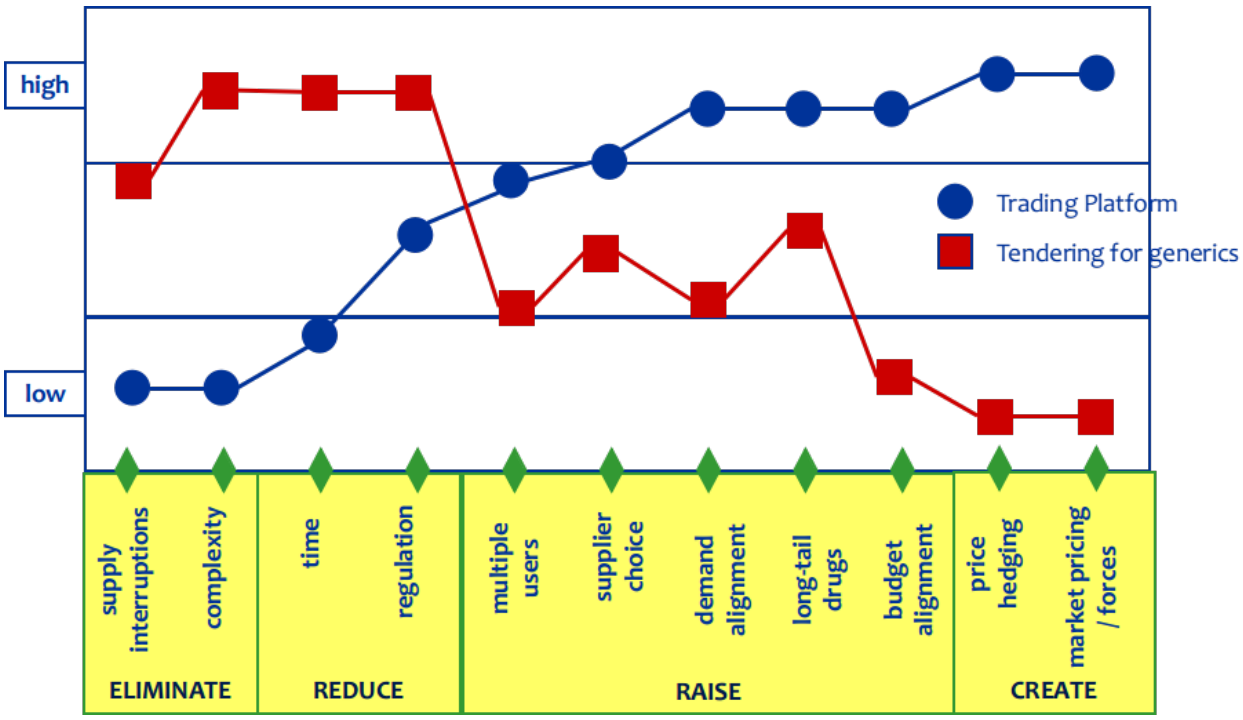


Figure 3: Platform trading compared to standard tendering Source: Tremblay

Compared to Standard Tendering, the trading platform approach offers key benefits:

1. **eliminating**
    1. supply interruptions,
    2. to a degree the complexity of medicines markets by introducing pricing and transaction transparency to remove layers of intermediaries,
2. **reducing**
    1. the time to procure, from months to minutes, and to real-time requirements
    2. assisting pricing regulators in reducing the complexity of the pricing regulatory process and burden which is placed on both buyers and sellers,
    3. creates for regulators a simpler regulatory environment,

3. **raising**
    1. the number of suppliers to markets and increasing supplier choice, to avoid the perverse consequences of tendering as well a better aligning supply to demand, to reduce waste arising from dated stock and over manufacture,
    2. availability of long-tail (what the industry calls legacy drugs), which are still in demand but often supplied by monopoly suppliers, by reducing the ability of such suppliers to game medicines supply,
    3. ability for payers and manufacturers to better align their costs with their business, so manufacturers do not over produce, buyers do not over buy, with these costs savings accruing to the bottom lines of both sides of the market,
4. **creating**
    1. the possibility of hedging medicines pricing, particular for expensive new medicines, by shifting the discussions to more balanced pricing discussions and demand management,
    2. bringing market forces to bear on pricing,
    3. substantial transparency with rich real-time information to facilitate more accurate forecasting of supply with demand.

2.6 Would there be payer interest?

Four to five EU member states have expressed interest in pooled pricing models and common procurement of medicines.

A pan European medicines procurement platform respects the autonomy of member states to work collaboratively on medicines pricing and procurement, within the Single Market rules (e.g. cross-border movement of products, price transparency).

There is interest around the world on ways to better procure medicines and drive down medicines prices using market mechanisms rather than regulatory force alone. Countries with an expressed interest in this include Canada, which wants a national drug procurement platform, the United States, and Africa, where affordability and supply disruption are common; other markets where opportunities exist include ASEAN nations, which are looking at creating a single medicines market, and Gulf Cooperation states, where medicines policies are stressing public

treasuries despite their wealth.

2.7 What about Suppliers?

The sell-side generic manufacturers are likely to be the early adopters as pricing is a key to their value proposition to payers.

Branded generic manufacturers would likely adopt if priced and procured through the platform to replace tendering.

The pharmaceutical companies, with monopoly pricing/products, may resist early adoption, preferring the negotiated entry model. It will be necessary to demonstrate that this approach offers a win/win to all, to help payers forward price new drugs prior to entry, deliver price transparency and convergence across borders. Given a new medicine is alone in its class (without a competing product) for around 13 months, it is likely that forward pricing within classes of medicines would be possible.

Based on sales the figure identifies the top pharmaceutical companies and their global market share. For branded prescription medicines market share is more complex as it depends on the extent to which a specific medicine has a (near) monopoly position in treatment.

It is unusual for a pharmaceutical company to have more than 10% overall market share.

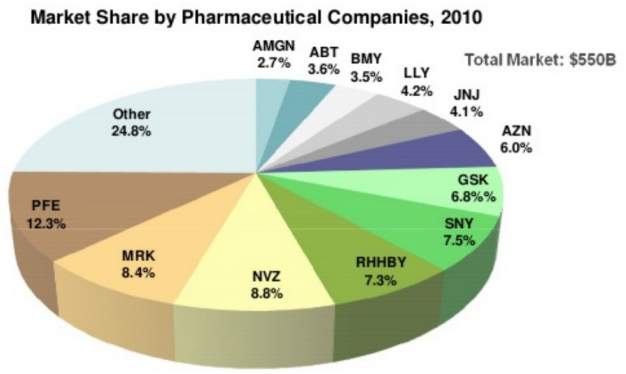


Figure 4: Market share, 2010, illustrative of scale

With respect to generics, a few companies have large share and are likely to be keen early adopters. Smaller suppliers will benefit as national SME (small medium enterprise) strategies are enhanced to enable new market entrants.

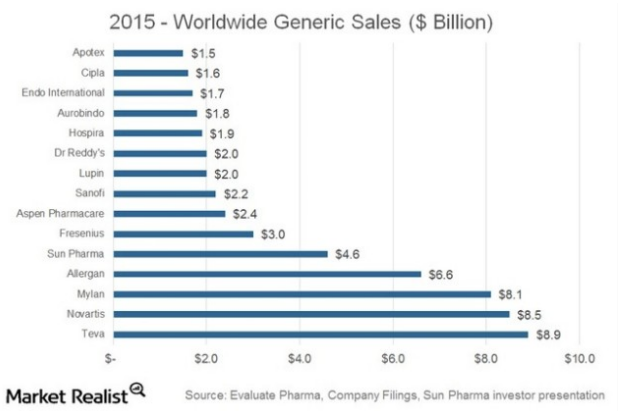


Figure 5: Generic sales, illustrative of scale

3 Can there be a trading market in medicines, i.e. are medicines fungible (interchangeably tradeable)?

Medicines fungibility may mean:

1. equivalence in the medicines active ingredients so there is direct substitution;
2. equivalence of the medicines in terms of achieving the same clinical benefit in the patient and can be substituted on that basis;
3. medicines in the same drug class have a similar chemical structure and the same mechanism of action (the biochemical reaction at the molecular level: the pharmacological result), a related mode of action (the functional reaction at the cellular level) and/or treat the same disease;
4. medicines with the same International Nonproprietary Name (unbranded generic medicines).

Branded generics compete for consumer attention based on brand values but are fungible in respect of the active ingredients and product claims under their marketing authorisation, subject to variations arising from dosage, package size and delivery system.

Biopharmaceuticals (biosimilars) use living organisms in their manufacture and therefore there is less assurance of complete fungibility.

An objective of the European Medicines Agency's Identification of Medicinal Products (IDMP) initiative is to achieve common information on medicines, which will underpin evidence of product equivalence based on agreed and common information and may have an impact on evidence for fungibility.

3.1 How are transaction settlement, clearing and risk managed?

Settlement for value is distinct from settlement for delivery. A trading platform deals primarily with enabling a mechanism to arrive at an agreed price, thereby triggering, in some form, payment and fulfilment.

The current supply chain, while complex, works to ensure doctors, patients, pharmacies and public authorities get what they order. The trading platform does not need to interfere with the mechanics of the supply chain, only ensure that products enter it at an agreed price. It may reduce the number of intermediaries but may also bring market efficiencies of benefit to all.

Brokers are used in many pharmaceutical procurement transactions, and while they

do not usually take possession of the orders, act to connect a supplier, through a procurement order, to a logistics route to the buyer.

Critical design questions include:

1. How will payments be made and how will money be held and flow between buyers and sellers?
2. What if the preferred transactions are via purchase order and there is no actual cash payment?
3. How will authorisations to deliver to authorised suppliers (all actors in the medicines supply chain require operating licenses to handle medicines) be handled once evidence of payment or intent to pay as been made?

Non performance within a supply contract, such as non-delivery, represents a medicines shortage, common in single-soure standard tendering procurements. It is expected that the finer calibration of demand by removing the need to buy in bulk through multi-year contracts will remove risks of supplier failure, by enabling multiple suppliers to be party to in effect call-off contracts including for gaps in supply by being a supplier to a particular contract.

It is intended that optimisation of supply and delivery of medicines will be a functional benefit.

3.2 So, how will pricing authorities view this?

There is no agreed methodology for medicines pricing.

Each country has a public authority which is responsible for negotiating or setting medicines prices in that country, using various analytical tools to arrive at prices in discussion with pharmaceutical suppliers, through legislation that sets prices or controls profits.

Trading of medicines will need to be able to deal with a ratchet effect that lifts drug prices above the pricing authority's ceilings as a function of trading, as well as a downward rachet to set new trading floors.

However, a trading platform will alter the regulatory and pricing logic currently used around the world.

4 What is the current structure of medicines markets

The medicines market is global, and involves influential regulatory or controlling factors.

It is governed by country-specific medicines regulations, which determine what medicines may be legally placed on the market, and related regulations on quality of the medicine, its manufacture and how it is marketed. There is convergence internationally around many areas of quality control; however, medicines licensing is not portable from country to country (the EU has a single market which enables portability of a marketing authorisation in one country to be used in other member states).

These vary by country and key variations can be mapped to show how the global market segments have common and divergent features.

It is also governed by specific mechanisms to control the price of medicines and how much public payers will reimburse for the use of a medicine. The price of a medicine does not necessarily equal what the public payer or insurer will pay for the medicine, as cost-sharing with patients is common in many countries through co-payments or supplementary insurance.

These features vary by country and can be mapped to show how price and payer decision making determines public pricing.

Private purchase of medicines is not usually affected by the public payer pricing and the private market has different policies regarding pricing and reimbursement. This is common in many countries, the effect of which is to create partitioned public/private healthcare systems and markets (e.g. Brazil, Saudi Arabia, India). This causes distortions in pricing as well as ‘gaming’ of pricing between partitions.Countries are commonly organised into archetypes, defining common features which affect how that market behaves in terms of pricing, reimbursement and regulation.

Market archetypes define the primary drivers of medicine pricing. Pharmaceutical industry uses market or payer archetypes to segment countries for the purposes of pricing. Within market archetypes, pricing is often calibrated to the country GDP.

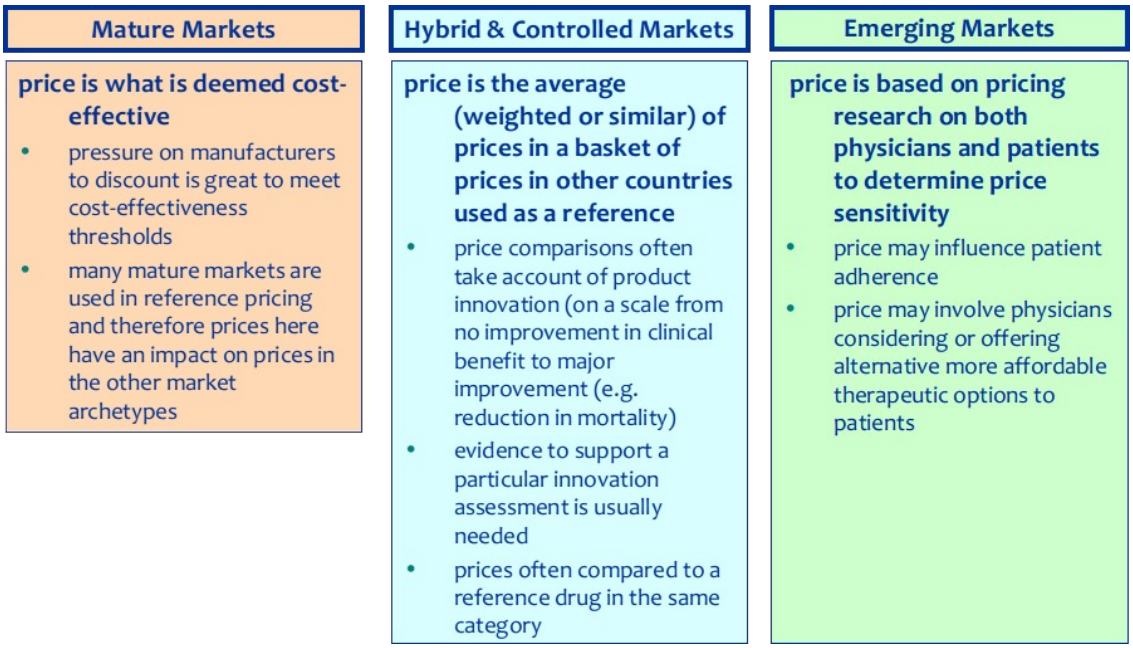


Figure 6: Simplified market archetypes Source: Tremblay

5 What is a drug price?

A medicine can have its price determined in a number of ways: these are various mechanisms currently in use. This is not a complete taxonomy.

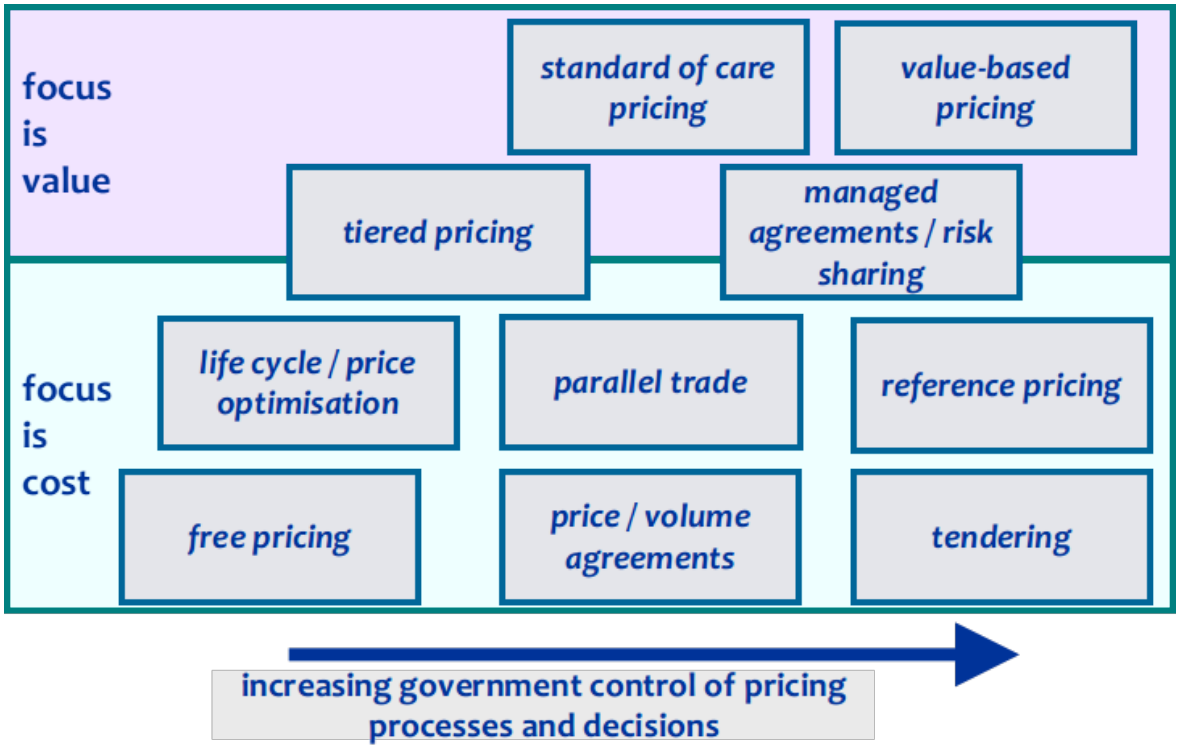


Figure 7: What is a drug price?

From the perspective of procurement, payers set various conditions on the price of the medicine itself.

As a medicine moves through the supply chain, the price alters (usually goes up) at each of these stages as intermediaries add their costs or additional charges are included, until the final price is set for the end-user, as in Figure 8.

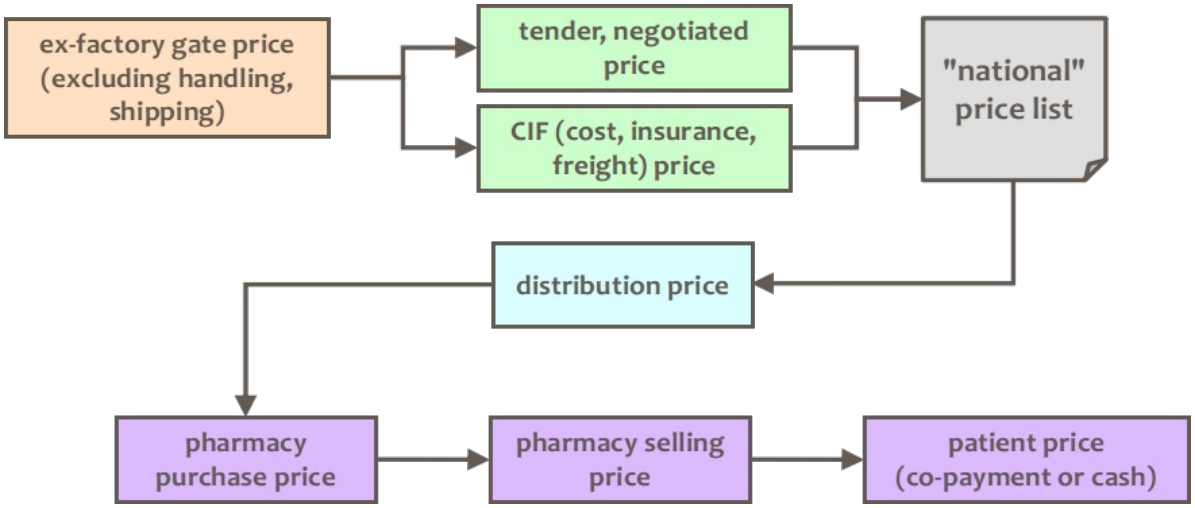


Figure 8: Price setting across the supply chain

Stage 1: manufacturer's selling price (perhaps with insurance and freight added in)

Stage 2: landed price in the country of delivery

Stage 3: wholesale selling price (e.g. private sector) or Central Medical Stores price (e.g. public sector)

Stage 4: retail price (private sector) or dispensary price (public sector)

Stage 5: dispensed price either to the patient directly or in hospital use.

5.1 External reference pricing

Many countries use external reference pricing to establish the price of a medicine, based on a calculation of the publicly known price of a medicine in a basket of countries.

These act as ceilings for prices and a trading platform may need to be able to work with these price constraints. It is perhaps more likely that reference pricing would be replaced by something like a 'GDP-multiplier' to reflect national purchasing power, but that remains to be assessed.

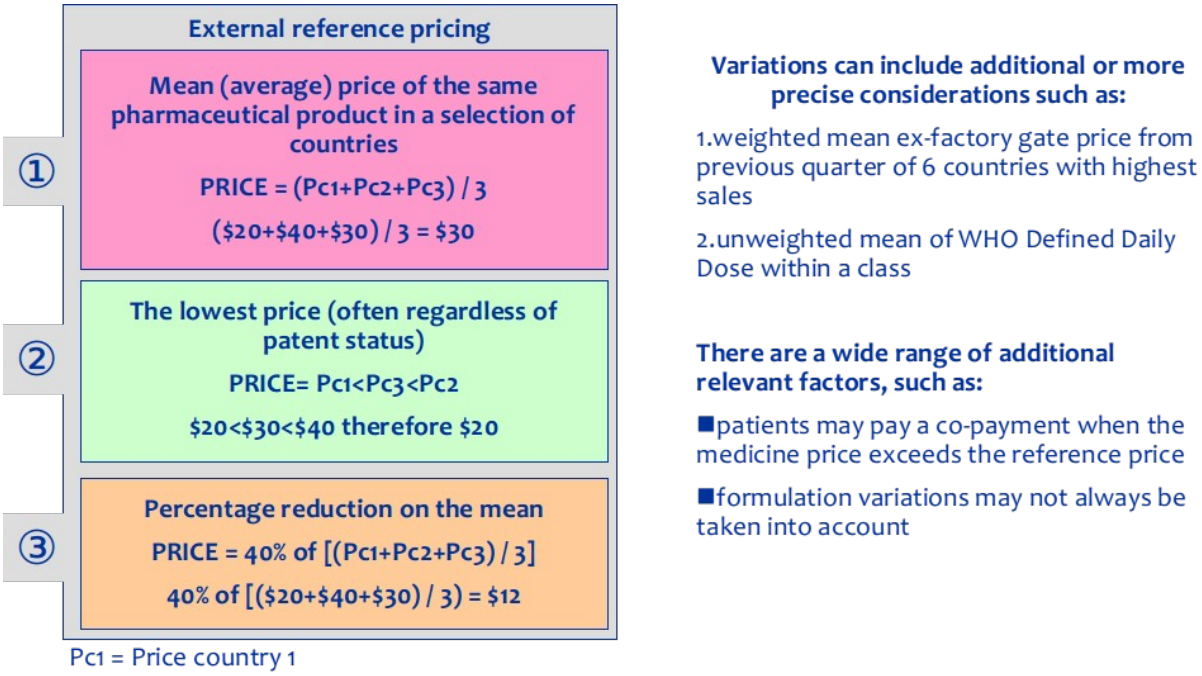


Figure 9: External reference pricing (inter-country comparison) [Source: Tremblay]

5.2 Market research

Market research is frequently used to determine whether a medicine would be affordable in a specific country and this is often done through direct interaction with public purchasing authorities and clinicians to determine the features they value in a medicine and which are then used to assess what launch price to use that prices that value.

The figure is a relatively basic model but is illustrative of the pricing approach used to establish 'pricing corridors', within which there is supplier pricing flexibility to adjust prices in negotiations with authorities. This approach is particularly sensitive to 'discounting' pricing methods, price-volume agreements, and capitation,

but fails with value based pricing, conditional pricing, coverage with evidence development, outcomes guarantees and similar structured pricing approaches.

Once a price is set in a country, it is usually impossible, under regulations, to raise it later apart from approved uplifts for inflation; it is not uncommon for approved pricing increases not to be done efficiently, while in other cases, corporate increases in revenue may only arise from inflation uplifts and not reflect increased sales.

Within a corridor, for instance, it may be common for a country manager to have the authority to offer a discount from the ceiling price without needing approval.

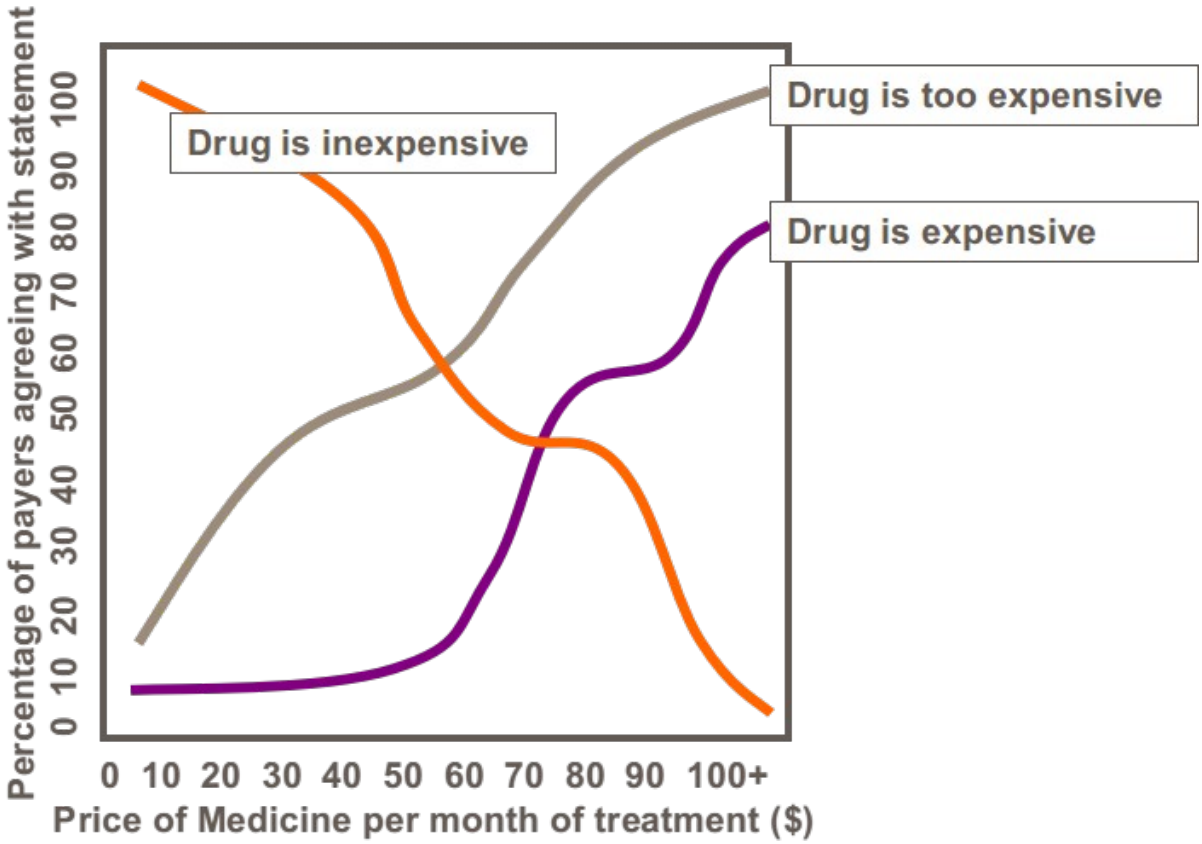
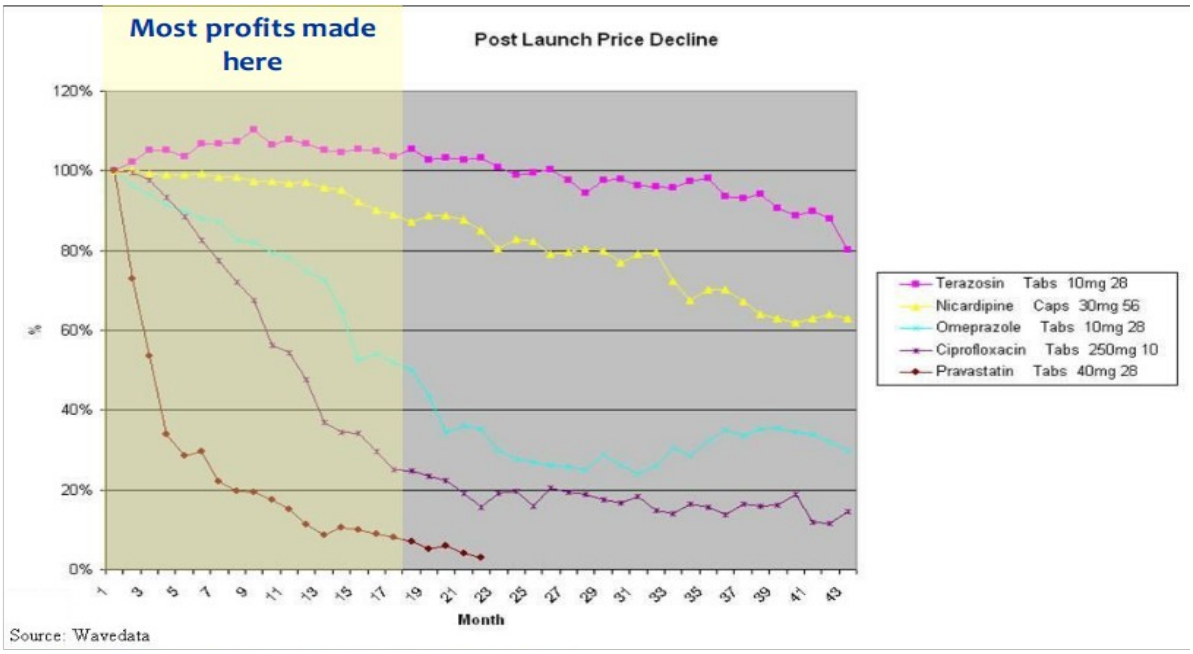


Figure 10: Westendorp-type way to determine drug affordability Source: Tremblay after van Westendorp

5.3 Price decay

Over time, prices decline as new products enter the market, and as companies shift a product toward legacy (established) products where they are managed differently, or if the product fails to achieve the company's market share objectives.



Source: Charles Joynson - Managing Director - Wavedata Ltd

Figure 11: Example of price decay [Source: acknowledged]

5.4 Price equalisation

Price equalisation can produce dramatic price declines following loss of patent protection as prices converge to a lower price band amongst competitors over similar time frames.

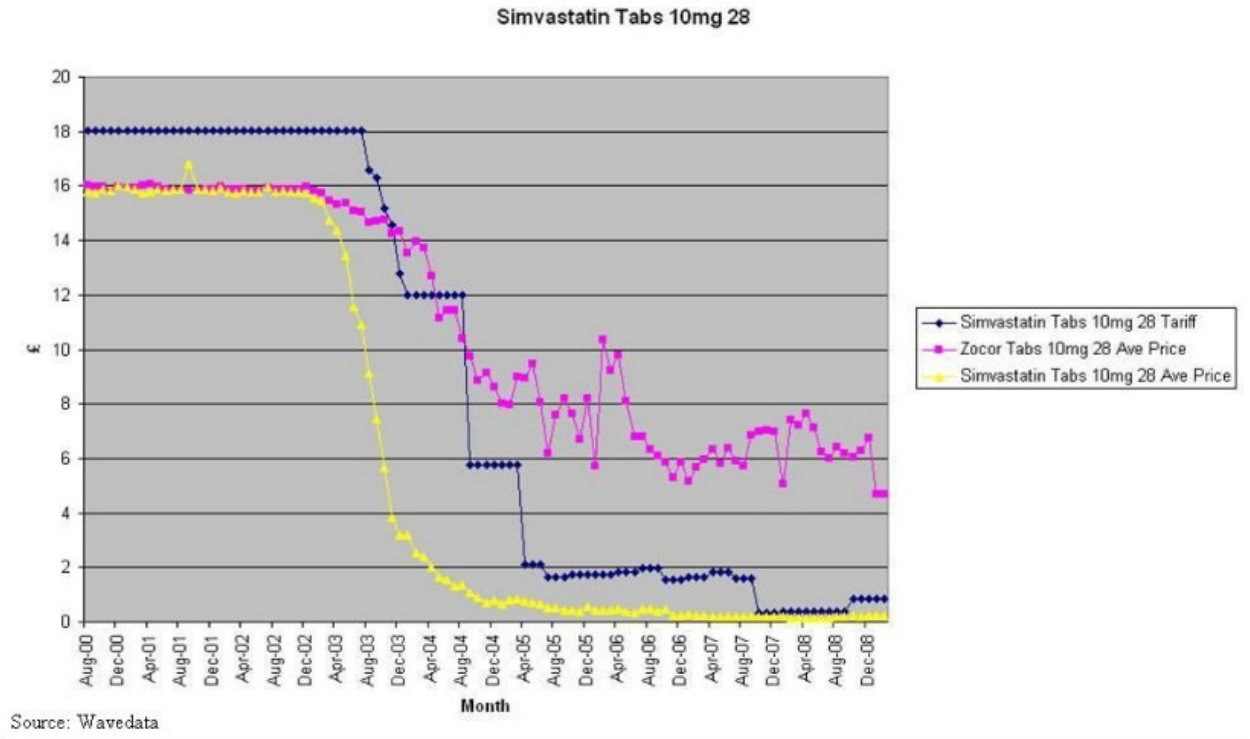
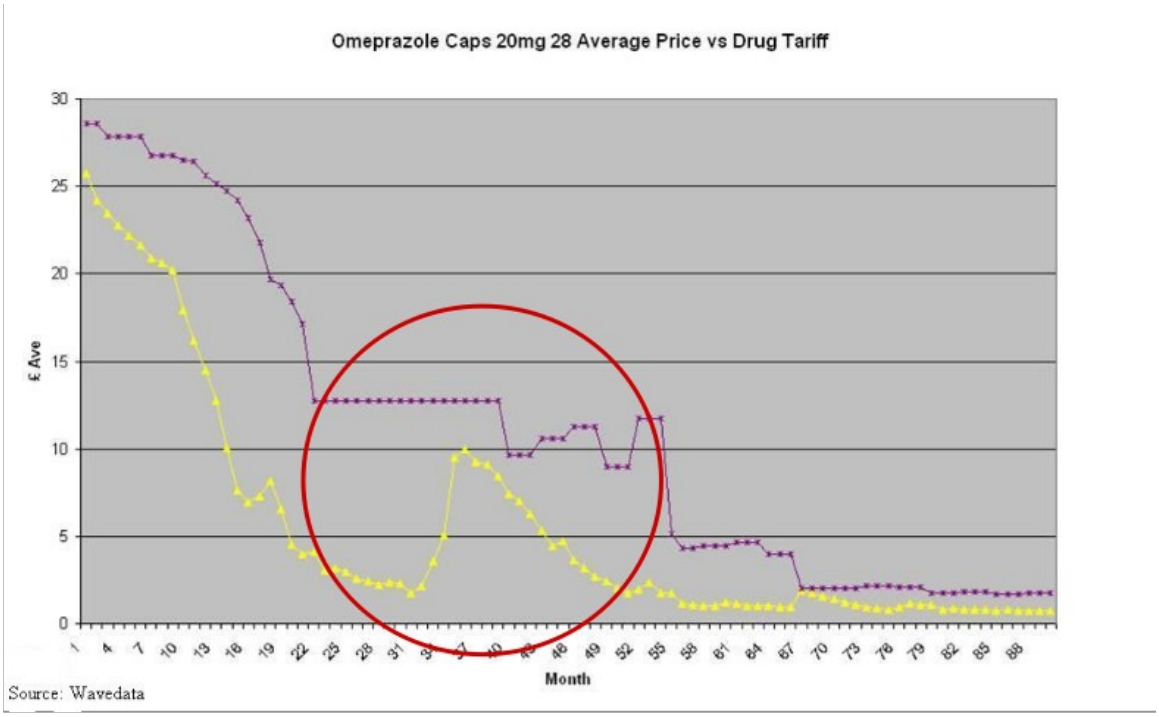


Figure 12: Price equalisation [Source: acknowledged]

5.5 Dead cat bounce

This arises from artificial expectations of price increases while a competitor will drive down the price on the market for all. The bounce is temporary and occurs when expectations of continued price increase for a supplier is not born out by subsequent market behaviour and the price then drops again to trend.



Source: Charles Joynson - Managing Director - Wavedata Ltd

Figure 13: Dead cat bounce [Source: acknowledged]

5.6 Drug flip pricing

This occurs under monopoly supply for generics and is avoidable with greater market access for competitors.

It is a known risk when a product is taken over by a new owner. It can be caused when a supplier 'games' the market entry rules by withdrawing the medicine from the market, then seeking a new market application. Price increases can be eye-watering and from a regulatory perspective may be disconnected from real world use.

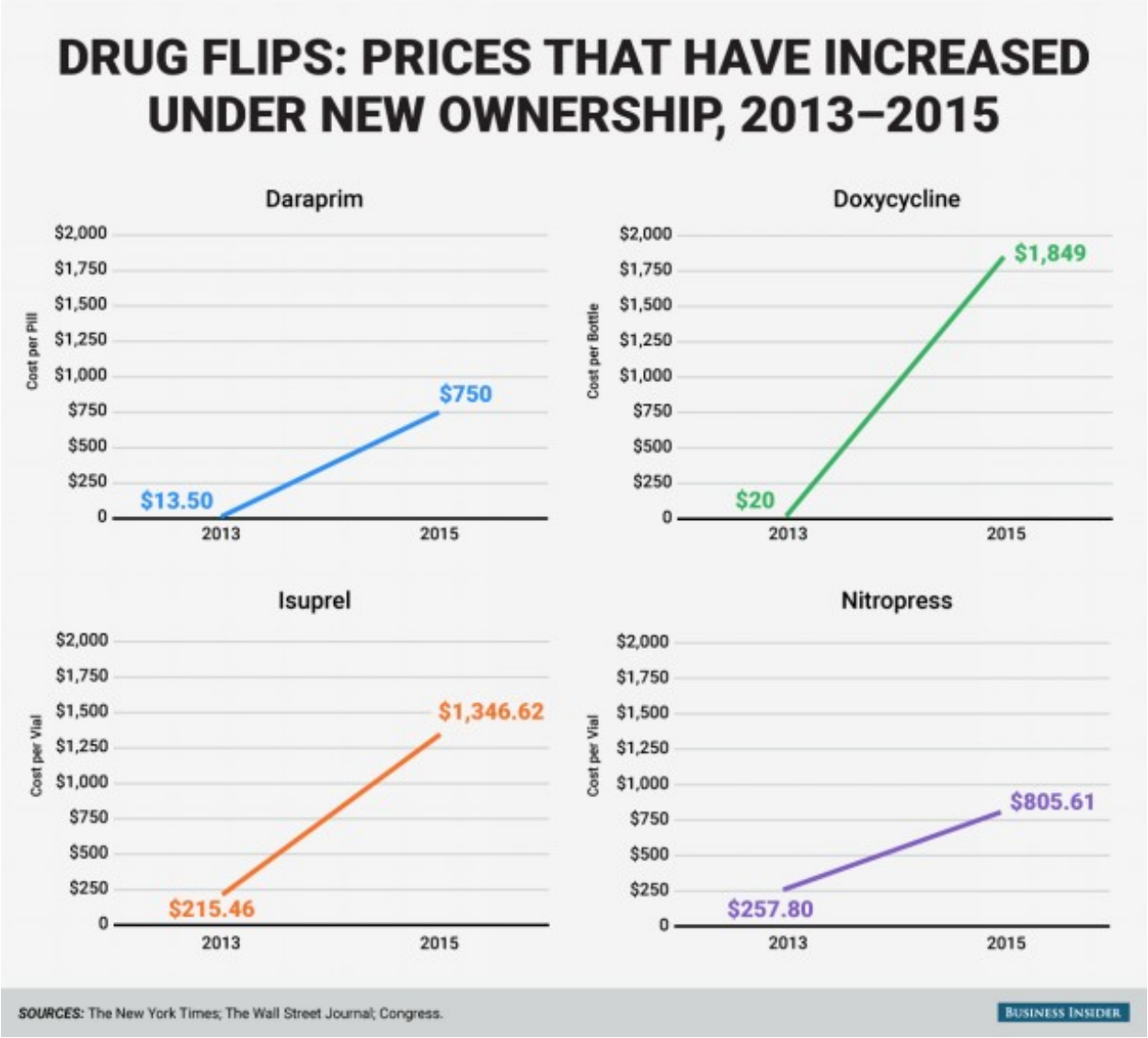


Figure 14: Drug flipping [Source: acknowledged]

5.7 Forward pricing

This is a schematic analysis of how forward value-based pricing for future expensive branded prescription-only medicines might work on a trading platform. The model aligns the following factors influential in pricing: community risk to balance treatment population and treatment risk, and price corridors at launch. These represent the two sides of the market, the former is the payer's concern and the latter is the supplier's concern.

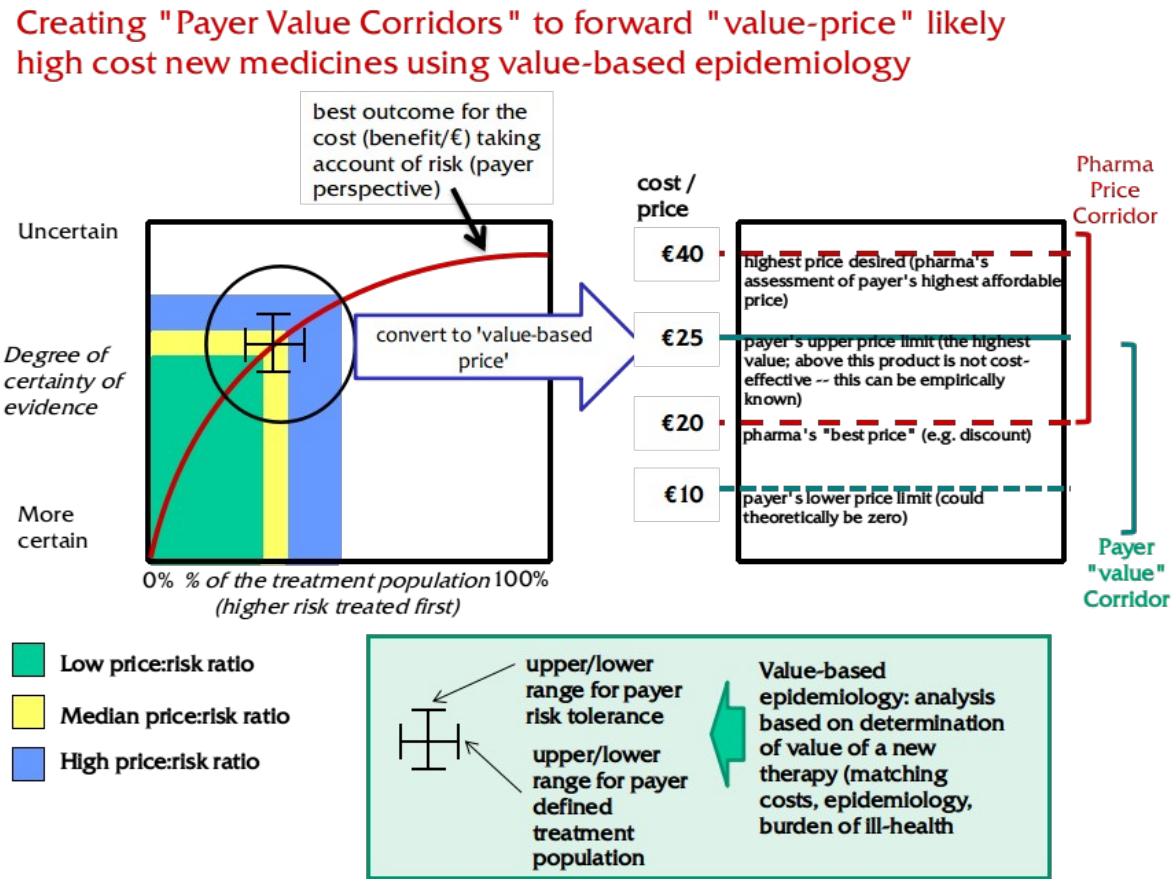


Figure 15: Forward pricing Source: Tremblay

For more information and details on the white paper, please contact the author.