The Art of Pricing in the Pharmaceutical Industry

by Infosys Lodestone

Take the guesswork out of pricing and transform your bottom line.
After Innovation, Smart Pricing is the Single Most Important Source of Competitive Advantage for Pharmaceutical Companies

In a world full of smart cards, smart phones, smart money and smart drugs, whatever happened to smart pricing?

In our discussions with pharmaceutical executives, we continually hear that the idiosyncrasies of the pharmaceutical industry make general pricing theory difficult to apply.

To a large extent they are correct. Pharmaceutical executives don’t just balance price between customers and competitors, they also deal with prescribers, health authorities, pricing authorities, reimbursement authorities, independent health-economic advisors and a host of other stakeholders divorced in the buying process.

Many companies have capitulated. Others however, have recognized that these complexities provide a rich source of competitive advantage. They are coming to grips with concepts such as game theory and systems thinking to focus and structure essential information about the players in the pricing game. They are using smarter, more sophisticated tools to formulate and value pricing strategies. They are discovering the inroads to break away from their peers and transform their bottom line in the process.

Pharmaceutical executives face a whole plethora of strategic questions related to pricing, the nature of which changes significantly throughout the life cycle of their products:

**Pre-launch phase:**
- What price is achievable in different indications?
- What is the price to volume relationship by indication?
- What trial comparator will support premium pricing?
- Based on future reimbursement scenarios, what areas should we invest R&D funds in?
- How do we determine the value of a new innovative product?

**Launch and expansion phase:**
- At what price should I launch this drug?
- On what basis should I segment the market?
- What pricing strategy should I adopt in the different countries?
- How do I deal with cross-border trade?
- Should I use bundling or other complex pricing schemes?
- How can I predict competitor future price launch?
- How should I react to branded competitor price moves?

**Maturity and decline phase:**
- How can I shift the focus away from price?
- How do I adapt my product proposition to maintain sales?
- What is my price setting against generic products?
- What other defence strategies are viable against generics at patent expiry?
- What options should I take anticipating the end of life cycle: strategic alliance, harvesting, retrenchment...

The purpose of this paper is to focus on the concepts and tools to answer these questions. In doing so Infosys Lodestone aims to better equip pharmaceutical executives to formulate and sustain winning pricing strategies throughout the life cycle of their products.
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1 Pre-launch phase

1.1 Prevalent Strategic Pricing Questions

Before the launch of a new drug, pharmaceutical executives are typically challenged finding answers to following questions:

- What price is achievable in different indications?
- What is the price to volume relationship by indication?
- What trial comparator will support premium pricing?
- Based on future reimbursement scenarios, in which areas should we invest R&D funds?
- How do we determine the value of a new innovative product?
1.2 The Price Finding Problem

Price finding for a blockbuster potential drug in the run up to launch is probably the single most important value creating or destroying decision for marketing executives in the pharmaceutical industry.

Launch too low and you will leave money on the table from customers willing to pay more. Elastic markets will create un-anticipated demand for your product, driving you into capacity constraints and forcing you to put customers on backlog, adversely affecting your reputation and denting brand equity. Not a pretty picture.

Launch too high and you will pass on money from customers willing to pay a profitable price. The prospect of high margins and the un-served market will attract competitors. Furthermore, lower than anticipated volume may cause you to leave capacity idle, lose out on economies of scale and experience curve effects. Not a pretty picture, either.

Economic theory suggests the optimal launch price can be found from the customer’s price response curve and the variable cost profile of the product. Let’s assume for the sake of argument that management has a single period, profit maximization objective and faces a linear price response curve. Price finding is then reduced to finding the rectangle with the biggest area within the boundaries of the price response curve and the variable unit cost.

In the graph above, the optimal price $P_{opt}$ yields a profit contribution of $(P_{opt} - V_{cost})Q_{opt}$, easily some 30% higher than the profit obtained from the price $P_{sub}$ be it $(P_{sub} - V_{cost})Q_{sub}$.

A linear approximation of the price response curve leads to an interesting rule of thumb executives can apply to do some rough price finding; The optimal launch price sits in the middle of the customer’s highest willingness to pay ($P_{max}$) and the variable unit cost ($V_{cost}$).

Although clearly simplistic, price-finding discussions benefit from using this type analysis as a starting point. It gives an instant feel for the business at stake and reinforces the interplay of volume, price sensitivity, willingness to pay and cost.
1.3 Triangulating the Forces of Value

Value and price are at the heart of any economic transaction. In simple terms, a customer will buy a product if, in his eyes, its value is greater than the price charged by the seller. Unfortunately customers do not always understand how the extra services and intangible attributes affect their lives, or in other words, how to translate them into real dollars.

Effective marketing and sales strategies can change what customers are willing to pay by making customers see the value of the entire product and service package.

Value can be thought of as utility, or the maximum price that a rational, fully informed customer would be willing to pay. We like to think of this utility as being derived, not from a product, but from a product proposition.

«Proposition» is a much broader notion than «product». It recognizes that the customer gains usefulness, not just from product attributes, but also increasingly from service attributes and intangible attributes.

1. **Product attributes** group value-driving features that are strictly related to the product itself, such as efficacy, safety, interactions, side effects, contra-indications, dosing, dosage, presentations, formulations, etc.

2. **Service attributes** group value-driving features that go beyond the product itself, such as value-added services, quality of advice, access to information, product availability, response time, etc.

3. **Intangible attributes** group value-driving features such as brand strength, reputation in the franchise, opinion leadership, ethical conduct, etc.

In making a **buying decision**, the customer will relate the value of the proposition to the price of the best alternative. During this evaluation, the differentiation value perceived from the various attribute performance levels is taken into account. Differentiation value may be negative for those attributes where the new offering is weaker than the reference proposition.

Research shows that the customer always searches for a reference, irrespective of novelty, be it other products or simply the local purchasing power in less developed countries.

With the launch of Celebrex™ [Pharmacia, now Pfizer] and Vioxx™ [Merck] early 1999 a new class of pain relievers, called COX-2 inhibitors, was introduced into the market. Because they are easier on the stomach compared to traditional painkillers, they were quickly dubbed «super aspirins». Pharmacia and Merck were able to charge a premium of no less than 100% over incumbent references. Because of this attribute, it subsequently gained acceptance as chronic arthritis pain relief medicine extending. After Vioxx was removed from the market in 2004 because of concerns over increased risk of heart attack and stroke, Celebrex survived as the only drug in the cox-2 class of anti-inflammatory drugs. Early 2009 Celebrex is studied for use in prostate cancer.
1.4 Value Mastermind

But how do you go about estimating the price response for a **new innovative product** that hasn’t even received marketing authority approval?

Although many techniques exist for stimulating the response a customer may have on price, we feel that for breakthrough products customer surveys based on conjoint analysis techniques typically yield the most accurate results.

Conjoint analysis is an intelligent customer survey technique, based on statistical analysis. The power of this technique is that it calibrates the value of a proposition and each of its features in financial terms.

These features can be the **product, service** or even the **intangible** attributes of the value proposition. Conjoint analysis will help define the price the customer is willing to pay.

The question posed to the respondent reflects the buying process, where a choice needs to be made between several competitive alternatives with different attribute levels and prices (Figure 1.4).

Which of the following drugs would you prescribe to a newly-diagnosed Ortho-arthritis (OA) patient: Male – Age 65 – Suffers from knee pain and consequent poor mobility – No other complaints?

Press button A, B or C to choose!

<table>
<thead>
<tr>
<th>Drug A</th>
<th>Drug B</th>
<th>Drug C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective pain relief in 60% of OA patients</td>
<td>Effective pain relief in 80% of OA patients</td>
<td>Effective pain relief in 90% of OA patients</td>
</tr>
<tr>
<td>Effective within 60 minutes</td>
<td>Effective within 2 hours</td>
<td>Effective within 30 minutes</td>
</tr>
<tr>
<td>Low risk of gastrointestinal side effects</td>
<td>Medium risk of gastrointestinal side effects</td>
<td>High risk of gastrointestinal side effects</td>
</tr>
<tr>
<td>$3 a day, not reimbursed</td>
<td>$6 a day, not reimbursed</td>
<td>$9 a day, not reimbursed</td>
</tr>
</tbody>
</table>

Figure 1.4: Conjoint survey – Game of mastermind

A conjoint survey unfolds like a little game of mastermind. Every time a choice is made among competitive alternatives, a bit of information on the respondents’ preferences is revealed.

On the basis of this information, a mathematical routine proposes a new combination of competitive alternatives with their attribute levels. As the customer progresses through the survey, a complete preference profile is built up.

In a realistic survey, 10 to 20 comparisons are usually sufficient to compute the value of each attribute level for the respondent.

Once the survey is completed, the program determines the **relative importance of the attributes** in the overall preference profile of the respondent. Mapping these preference profiles against respondent profiles is a powerful tool for market segmentation.

But more importantly, the big pay off of using **conjoint analysis** is in the **ability** to price a particular attribute performance level. Conjoint measurement touches the very heart of the value triangle, by pinning down how much a customer is willing to pay for reduced risk of gastrointestinal side effects and swift pain relief.

In Figure 1.5 the **values** for the 4 attributes are shown. We can see that when price increases from 6 to 8 dollars per day, this customer looses eight value points. In other words, one value point is priced at 25 cents. Reducing the risk for gastrointestinal side effects from high to low adds no less than 40 points or some 10 dollars per day.

<table>
<thead>
<tr>
<th></th>
<th>Drug DEF</th>
<th>Drug XYZ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Performance</td>
<td>Value</td>
<td>Performance</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>60%</td>
<td>35</td>
</tr>
<tr>
<td>Quick Actin</td>
<td>60 min</td>
<td>20</td>
</tr>
<tr>
<td>Side Effects</td>
<td>Low</td>
<td>40</td>
</tr>
<tr>
<td>Price</td>
<td>USD 8/day</td>
<td>19</td>
</tr>
<tr>
<td>Total</td>
<td>112</td>
<td>94</td>
</tr>
</tbody>
</table>

Figure 1.5: Game of mastermind – Example

Drug DEF is the new smarter drug. Although it is not effective with all patients, it has a differentiating feature highly valued by a segment of patients in the active, higher income segment of the population. Even with its slower acting characteristic, launching this drug at a 33% premium to the current reference product XYZ would significantly under-price the value to this customer. As far as this case goes, launching at a 33% premium would leave some 4 dollars and 50 cents on the table, every day.

But, one bird doesn’t call the spring. Nor, does one case make a price response curve. In order to aggregate the preference profiles within the surveyed customer segment we first need to translate the values into choices. Although care should be taken to select the appropriate rule, let’s just say, the physician will prescribe the drug that offers the highest value. It is now easy to see how we can aggregate various preference profiles into a **price response curve**.
The graph above stylizes the price response curve that was derived from the conjoint survey for Drug DEF. Marketing originally planned to launch the novel product in the top end of the therapy class at 8 dollars a day. The conjoint survey exposed that prescribers attached a much higher value to the product largely due to the differentiating aspect of reduced risk of gastrointestinal side effects. Furthermore, the price response curve showed an interesting flat spot suggesting relative price insensitivity above the top end of the therapy class. The product was launched at 11 dollars. In spite of the launch price being almost 40% above management’s original intentions, sales volume beat the original budget by 15%.

It is important to recognize that the price response curve is valid only as long as competitors do not change their prices in reaction to your launch. We therefore feel conjoint analysis is a superior tool to find price in markets with limited competitor interaction. This is typically the case when the product creates a new therapeutic class or sub-class or at least presents a significantly differentiated proposition.

On occasion we see claims being made that conjoint analysis allows for an assessment of the impact of competitive pricing action. We suggest such claims should be viewed with caution. Conjoint analysis tools are not designed to handle dynamic competitive interaction and feedback over multiple periods.

A game of chess is not won by thinking one step at a time. Likewise, a pricing game is not won by relying on conjoint analysis alone. To think ahead in pricing you need to bring game theory and systems dynamics into play.

The application of Game Theory and Systems Dynamics to develop competitive pricing strategies is addressed in section 2.4 «When competitors start interacting».
1.5 Can the Real Customer Please Stand Up!

Up until now we’ve only talked about *the customer*. But who is the customer for a pharmaceutical offering?

In most **consumer industries** the buying process is nicely streamlined. One and the same person identifies the need, compares alternatives, chooses what product to buy, bears the cost and enjoys the full usefulness of the purchase. The customer is easily and uniquely identifiable.

In **health care** the buying process is somewhat more complicated. Pharmaceutical companies don’t just clinch the sale with the **patient**. They also deal with **prescribers, pharmacists, health authorities, pricing and reimbursement authorities (insurers), independent health-economic advisors and a host of other stakeholders** who are involved in the buying process. The customer is an amorphous creature with multiple heads and a manic-depressive temper.

Amorphous as it may be, the identification of *the customer* is of prime importance in the assessment of preference profiles and willingness to pay. If you don’t know who is buying, price finding falls without object.

So what defines the customer? We strongly believe the forces that act on the buying process to influence the transaction outcome define the customer. The table below reflects this for typical pharmaceutical retail products.

### 1.5.1 OTC

For Over The Counter (OTC) medication it is typically the patient controlling the entire buying process, although there may be a large influence from others. Consequently, Value triangulation, the building of preference profiles and price response information is centred on the patient.

### 1.5.2 POM without reimbursement

For Prescription Only Medicines (POM) without reimbursement status, the dynamic is more interesting. In most European countries, drugs falling into this category can be considered wellness/lifestyle medications or are aimed at treating minor disorders.

In the past, the physician was considered the dominant force in the buying process. In many cases today however this can be seriously questioned. Disease management communities, self-diagnostic tools, liberated Direct-To-Consumer (DTC) advertising and ubiquitous medical information in general have all encouraged and put substance to patient emancipation.

Since the FDA altered its guidance for broadcast prescription drug ads in the US in 1997, DTC marketing has sky rocketed from $1.1B to over $2.5B in 2000. The impact on sales has been impressive: 8% of consumers exposed to DTC ads asked their physician for specific drugs and their request was honoured 70% of the time! Whether this should be considered a grace or a curse is yet another discussion...

<table>
<thead>
<tr>
<th></th>
<th>Over the Counter</th>
<th>Prescription Only Not Reimbursed</th>
<th>Prescription Only Reimbursed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identifies need to treat</td>
<td>Patient</td>
<td>Physician/Patient</td>
<td>Physician/Patient</td>
</tr>
<tr>
<td>Compares alternatives</td>
<td>Patient</td>
<td>Physician/Patient</td>
<td>Physician/Patient</td>
</tr>
<tr>
<td>Selects best alternative</td>
<td>Patient</td>
<td>Physician/Patient</td>
<td>Physician/Patient</td>
</tr>
<tr>
<td>Authorises purchase</td>
<td>Patient</td>
<td>Physician</td>
<td>Physician</td>
</tr>
<tr>
<td>Bears the cost</td>
<td>Patient</td>
<td>Patient</td>
<td>Government/Patient</td>
</tr>
<tr>
<td>Consumes usefulness</td>
<td>Patient</td>
<td>Patient</td>
<td>Government/Patient</td>
</tr>
</tbody>
</table>

Table 1.1: Who is the customer of health care products?
Patient emancipation has caused a shift in the balance of power in favour of the patient. In some countries the ability and practice of patients to shop physicians further amplifies this shift. Indications such as obesity epitomise this movement, with the patient often single-handedly deciding on the need to treat and the preferred pharmacotherapy.

Novartis R&D executives initially questioned the scale-up costs to develop a possible orphan drug such as STI-571. But after a third-party web site posted the news about the drug’s development and initial clinical success in limited trials, Novartis was bombarded with requests from patients to enrol in clinical trials and to bring the product to market. Ultimately, Gleevec™, the branded drug product, became the fastest ever FDA approved drug...

In many price finding efforts and conjoint studies particularly, we feel the prescriber is overemphasized. Failure to recognise the balance of power in the buying process can seriously distort relevant measurement of value and compromise price finding.

1.5.3 POM with reimbursement

For Prescription Only Medicines with reimbursement status, the government becomes involved, joining the patient and the prescriber to personify the customer.

It is important to recognise that reimbursement authorities have a very different perspective on value, emphasizing different attributes in the product dimension of the proposition and de-emphasizing service and intangible dimensions all together.

In assessing value, the reimbursement authorities will typically focus on therapy outcome and cost effectiveness. Unlike patients they will have limited or no consideration for Quality of Life aspects. Unlike prescribers they will have limited or no consideration for service attributes unless they directly influence therapy outcome.

The pharmaceutical industry is strongly lobbying with health authorities to shift away their focus from drug price as the key target to safeguard health care budgets. Despite the fact that prescription drugs account for only a tiny fraction of total health care expenses – only $0.10 out of each health care dollar in the US – governments almost exclusively have targeted the pharmaceutical industry to make up for the budgetary deficits in health care.

Figure 1.8: Patient versus prescriber perception of value proposition
«Single emphasis on the cost of pharmaceutical products can have a dramatic effect on public health as demonstrated in the UK where studies showed that due to the low level of drug spend in chemotherapy – £0.95/capita in the UK compared to £6.24, £3.81 and £1.29 in Germany, Italy and France, respectively – the survival rate for UK cancer patients was significantly lower than the European average for all major solid tumors». Anno 2009, anecdotal evidence suggests that these differences remain materially the same.

The narrow focus on cost effectiveness typically drives direct measurement and communication of value through health economic analysis. The rich information on patient and prescriber preferences obtained from conjoint analysis is dispensed as inadmissible in reimbursement negotiations.

It is not hard to see how a government’s willingness to reimburse can diverge heavily from a patient’s willingness to pay. This poses pharmaceutical executives with an interesting dilemma. What do you do when health economic arguments support a reimbursement level far below a patient’s willingness to pay? Some companies like Pfizer and AstraZeneca are openly considering not launching new drugs in countries where price controls are raising unacceptable barriers for profitability such as France and Japan.

«The cost of medicines reflects their enormous value – to patients, society, and the health care system. The industry warns that if drug prices are regulated, pharmaceutical companies may have less incentive to create new medicines because the costs will not be recoverable.»

Finding the optimal price under such conditions prompts three basic questions:

1. How big is the value surplus recognized by the patient in monetary terms?
2. How and to what extent is the premium over reimbursed price transferred?
3. Who is impacted by the transferal and how does it influence the buying decision?

Our preferred approach to answer the first question has been explained under heading 1.4 «Value Mastermind». Question 2 and 3 prompt us to explore government cost containment structures.

1. IMS Health, 2001
2. Prevention Magazine 2000
5. BPI 1998 and IMS Hospital & Retail
1.6 Price Finding in a Cost Containment Bonanza

Governments are determined to reduce public expenditure on health. In this endeavour, pharmaceutical companies have proved to be an obvious, although not always appropriate, target.

Drugs typically give a better return on health care spending than virtually any other health care option. Yet many governmental or private insurance plans have less coverage for drugs than for hospital or physician care, and many reimburse drug expenses at lower levels. As a result this practice encourages patients and the doctors who advise them to seek physician and hospital services when less costly drug therapies would have been preferable.

The introduction of ACE inhibitors for treating congestive heart failure allowed patients to avoid nearly $9,000 each in hospitalization costs over a 3-year period, meanwhile reducing mortality with 16%. The study claimed that the US could save over $2 billion a year.

In many cases, the use of prescription drugs has reduced the cost of other health care services. Even greater savings are possible. The decline in total spending due to greater use of prescription drugs is particularly notable in the treatment of cancer, heart disease, Alzheimer’s, AIDS and mental illness.

Furthermore, studies by Redwood & Gross, comparing international pharmaceutical spending controls across countries indicated that, while price controls induce lower prices, pharmaceutical expenditures (price x volume) are not contained.

Some of the most popular cost containment measures in Europe include reference pricing, patient co-payment, transfer to OTC status, generic substitution and prescribers budgets. No country relies on a single approach and there are variants of approaches.

Let’s explore how some of the best performing pharmaceutical companies handle price finding under these regulatory constraints.

<table>
<thead>
<tr>
<th>FR</th>
<th>UK</th>
<th>GER</th>
<th>ITL</th>
<th>ESP</th>
<th>POR</th>
<th>FIN</th>
<th>NET</th>
<th>BEL</th>
<th>IRE</th>
<th>SWE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control over POM launch price based on economic evaluation</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
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<tr>
<td>Control over price updates</td>
<td>✔</td>
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<td>✔</td>
<td>✔</td>
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<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Reference pricing</td>
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<td>Positive lists</td>
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<td>Negative lists</td>
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<td>✔</td>
</tr>
<tr>
<td>Control over profit</td>
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<td>✔</td>
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<td>✔</td>
</tr>
<tr>
<td>Patient co-payment</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
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<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
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<tr>
<td>Generic substitution</td>
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<td>✔</td>
<td>✔</td>
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<td>✔</td>
<td>✔</td>
<td>✔</td>
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</tr>
<tr>
<td>Prescribing behaviour monitoring</td>
<td>✔</td>
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<td>✔</td>
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<td>✔</td>
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</tr>
</tbody>
</table>

Table 1.2: Cost containment measures across Europe in 2007

1.6.1 Reference pricing

As from the early nineties, various governments in Europe have experimented with reference prices. Today, reference pricing typically takes the form of an averaging procedure over branded and generic products within a therapeutic class. Customers preferring a more expensive product pay the premium over the reimbursed reference price.

Not all countries set up the classes in the same way. In the Netherlands for example, almost every chemical entity is a class on its own. In many other countries, chemical entities that are considered therapeutic substitutes constitute a class. Furthermore, not all countries will have a reference priced class for a given chemical entity.

However, reference pricing is not the strait jacket it may seem. Ex-factory prices remain free and products don’t need to be priced at or below the reference. All too frequently, pharmaceutical executives display reluctance to price through any differential value of their products in a reference priced class.

We witnessed such discussions advising a leading pharmaceutical company in preparation for launch of their new improved anti-psychotic drug in Germany. Unlike previous generation neuroleptica, this product did not produce any of the Extra Pyramidal Side effects (EPS). The reimbursement authority did not see any efficacy or cost effectiveness upside and denied special status. The patient however saw significant upside in the improved product. A conjoint survey demonstrated that active patients especially attached great value to the absence of EPS and were relatively price insensitive. Inspired by the evidence, management found the courage to launch at a significant premium and step outside the price band of fully reimbursed references. Not pricing through zero EPS would have left serious money on the table.

Furthermore, the company in the example would have missed an opportunity to demonstrate price leadership and lift reimbursement levels of the reference group when other companies were set to launch their zero EPS propositions in the next 2 years.

<table>
<thead>
<tr>
<th>Country</th>
<th>Reference country</th>
<th>Basis of calculation</th>
<th>Compare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ireland</td>
<td>UK, Austria, Belgium, Germany, Spain,.. (9)</td>
<td>Average</td>
<td>Ex-factory</td>
</tr>
<tr>
<td>Norway</td>
<td>10 closest countries</td>
<td>Average of 3 lowest</td>
<td>Pharmacy</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Belgium, France Germany, UK</td>
<td>Average</td>
<td>Ex-factory</td>
</tr>
<tr>
<td>Portugal</td>
<td>France, Italy, Spain</td>
<td>Minimum</td>
<td>Ex-factory</td>
</tr>
<tr>
<td>Belgium</td>
<td>EU average</td>
<td>Average and minimum</td>
<td>Ex-factory and retail</td>
</tr>
</tbody>
</table>

Table 1.3: Reference pricing in 2007

11. Analysis of differences and commonalities in pricing and reimbursement systems in Europe, EASP, 2007
1.6.2 Patient co-payment

The aim of co-payment is twofold:

1. Shift some of the drug expenditure to the patient.
2. Reduce overall consumption by appealing to the price sensitivity of the patient.

The part of the drug cost that is shifted to the patient varies by country. In the UK for example, a system of fixed co-payments per pack is in place, which has prompted companies to bring larger presentations to market.

In most countries however, co-payment level is a percentage by reimbursement category:

1. Full or majority reimbursement for life saving drugs
2. Majority reimbursement for effective and valuable medication
3. Minority or no reimbursement for quality of life products

<table>
<thead>
<tr>
<th>Country</th>
<th>Type of Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>Flat, € 4.45 per medicine taken, generic or not</td>
</tr>
<tr>
<td>Belgium</td>
<td>No charge, 25% (ceiling € 9.30), 50% (ceiling € 15.49), 60%, 80%</td>
</tr>
<tr>
<td>Denmark</td>
<td>Under € 69: 100% of cost, between € 69 and € 167: 50%, between € 167 and € 390: 25%, over € 390: 15%</td>
</tr>
<tr>
<td>Finland</td>
<td>€ 8.41 + 50% of excess amount</td>
</tr>
<tr>
<td>France</td>
<td>35%, or 65% for normal drugs, 100% for ease drugs, 0% for long-term.</td>
</tr>
<tr>
<td>Greece</td>
<td>Flat fee: €4, € 4.50 or € 5, depending on the packet size</td>
</tr>
<tr>
<td>Ireland</td>
<td>Drugs Payment Scheme: never more than € 53 per month for prescribed medicines</td>
</tr>
<tr>
<td></td>
<td>No charges for certain types of patients.</td>
</tr>
<tr>
<td>Italy</td>
<td>Free for serious illnnesses, 50% for less serious, 100% for prescribed</td>
</tr>
<tr>
<td>Norway</td>
<td>Patient pays 36% (ceiling € 45 per quarter). 100% for less important drugs</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Flat fee + Deductible. Benefit in kind. Insured person is entitled to a qualitatively good package of medicines without it being necessary to make additional payment. Besides this medical package medicines can be supplied and charged to the health insurance funds up to the average price per standard dosage of medicines which belong to a certain classified medical package, with an additional payment to be paid by the insured himself.</td>
</tr>
<tr>
<td>Portugal</td>
<td>State contributes 70% or 40% of the cost of medicines on the official list drawn up by the health services.</td>
</tr>
<tr>
<td>Spain</td>
<td>40% of the price of medicaments to be self paid. There is a 90% reduction of the price for certain special medicaments, with a maximum limit €12.64.</td>
</tr>
<tr>
<td>Sweden</td>
<td>Up to € 100: 100%. Between € 100 – € 189: 50% of the cost. Between € 189 – 368: 25% of the cost. Between € 368 – 479: 10% of the cost. Above € 479: 0% of the cost</td>
</tr>
<tr>
<td>UK</td>
<td>Charge of GBP 6.10 (€ 9.74) per prescribed item</td>
</tr>
</tbody>
</table>

Table 1.4: Patient co-payment in EU in 2002
A conjoint survey at the patient level can be set up to support price finding under co-payment. Respondents make a series of choices between several competitive alternatives with different attribute and co-payment levels.

Any subsequently derived price sensitivity and price response information assumes perfectly informed and assertive patients. This hardly ever is the case. When interpreting co-payment conjoint surveys, management should be cognisant of the elements driving such imperfections. A few of the most prominent distortion drivers are highlighted below.

1.6.2.1 Life style versus non-life style products
Sometimes patients are willing to pay more for life style products even if there is no reimbursement of the product. Diseases like obesity with drugs as Xenical™ & Sibutramine™, or erectile dysfunction with Pfizer’s Viagra™, are perfect examples of markets that have been largely driven by patient demand irrespective of reimbursement status.

1.6.2.2 Patient assertiveness
Not all patients are well informed. Most of them rely on the prescriber and do not question the prescription. Some patients have no idea and dare not ask for additional information. Using DTC campaigns providing therapeutic information to patients, pharmaceutical companies in the US have been very successful in creating a consumer demand-pull complementing the traditional demand through prescribers2.

1.6.2.3 Acute versus chronic illness
When the prescription is written, the patient has not always the time, nor the competence to evaluate competitive alternatives. This is definitely the case for acute illness.

For a chronic disease the patient is usually better informed and has a bigger incentive to evaluate alternatives. Moreover, patients with a chronic life-threatening illness often are members of support groups where they share ideas and experiences with each other. It is not atypical for these patients to be better informed than their physician and to lead prescribing behavior.

1.6.3 Generics and therapeutic substitution
In 1994 the World Health Assembly passed a resolution considering the role of the pharmacist. Amongst other points it urges action by all governments, in collaboration with national pharmaceutical associations to make full use of the expertise of the pharmacist at all levels of the health care system.

The International Pharmaceutical Federation (FIP) already decided in 1997: «It is now clear that with appropriate exercise of medical and pharmaceutical judgement, medicinal products within a pharmacological class may be interchanged according to defined criteria and the needs of the patient without significant compromise of patient outcome.»

This means that substitution adds yet another customer to the buying decision in health care. One that can overrule a buying decision from the prescriber/patient.

There are two main forms of substitution, namely generic and therapeutic substitution.

1.6.3.1 Therapeutic substitution
Therapeutic substitution is the practice of dispensing an alternate chemical entity from the same therapeutic class for the drug product that was prescribed by a physician. One such example is dispensing procainamide for quinidine.

For each patient, a specific drug or combination of drugs has been or should be prescribed for a specific problem by the patient’s physician. Since the pharmacist doesn’t have available complete clinical information for specific patients and doesn’t possess the medical training to base a therapeutic decision on «therapeutic substitution» may result in the patient receiving a drug agent potentially lacking efficacy, producing life-threatening toxicity, or interacting adversely with other drugs the patient is receiving. Each of these are unacceptable consequences and therefore we believe any «therapeutic substitution» should be strictly controlled.

1.6.3.2 Generic substitution
This statement should not be construed to represent opposition to generic substitution, the act of dispensing a different brand or an unbranded drug product that is the same chemical entity and bio-equivalent to the drug product prescribed. A generic drug has the same active ingredient[s] as the brand name version, in the same strength or concentration. It has the same chemical name, dosage form, and route of administration, and produces the same therapeutic effect. Therefore proprietary for generic substitution is the only form allowed in most countries.
1.6.3.3 Power shift
If governments or reimbursement agencies give the power to the pharmacist to substitute the product, it is clear that there is a huge power shift in the buying decision.

In addition, this power shift can even be bigger if the pharmacist is accountable for the cash saving of the reimbursement agencies, or if he may share in the substitution savings.

Health care authorities determine what pharmacists may dispense when presented with a prescription and how pharmacists’ remuneration is set. In nearly all the European countries, the bulk of pharmacists’ income is derived from their margins on dispensed prescription medicines. In most of the remaining countries, they are paid a fee and compensated for the pharmaceuticals dispensed at cost. Other countries use a combination of both systems. In some cases the pharmacist can determine, or at least influence, which drug is dispensed. In such cases, they may well become influenced by the difference in income from alternatives. In order to favour particular medicines, pharmacists may receive incentives from authorities, pharmaceutical companies or wholesalers.

Substitution and the gain share schemes that governments wrap around it move the pharmacist to centre stage with dramatic implications for price finding and price structuring strategy.

The consumers will of course benefit from this situation. The consumer has a choice and can save some money. If the newly prescribed generic medication works as well as its brand-name counterpart, you may save some money. If it doesn’t work as well, you can ask your provider to reinstate the original, trademarked product.

In 2007, generic drugs accounted for only 16% of sales in the US, but a massive 63% of all prescriptions, up from 47% of prescriptions in 1999.12

In the EU, the use of generics is even more widespread [about 30% of sales on average] with strong differences between the member countries, ranging in 2007 fro≈≈tia.13

Figure 1.9: Generic vs brand name drugs: sales vs prescriptions in the US

12. The Ongoing Regulation of Generic Drugs, R. Frank, 2007
13. The Pharmaceutical Industry in Figures, Key Data, EFPIA, 2009
1.7 Capitation Pricing

1.7.1 Changing the name of the game ...

Rising health care expenditures, especially in Europe, are putting extreme pressure on governments to cut costs, with drug the prime target of cost containment measures.

As long as reimbursement discussions will continue to centre on prices for units of product, pharmaceutical companies will also continue to find themselves on the short end of the bargaining table.

To break this frame, pharmaceutical executives need to change the pricing paradigm and get unit pricing out of the equation when negotiating drug reimbursement.

A way to do this is by charging a price per capita, i.e., per patient, instead of a price per unit of product, hence the name ‘capitation pricing’.

Capitation pricing represents a fundamental shift in the mindset for pharmaceutical companies. Instead of merely pushing new drugs into the market, selling them at the highest possible price and hope you’ll have another blockbuster when the patent on your key drugs expires, Pharma needs to take control of a larger slice of the treatment pie by building on its extensive knowledge and superior information.

1.7.2 Critical success factors for capitation pricing

Based on the characteristics of the drug and the disease area, a particular drug may lend itself better to a capitation based pricing model.

1.7.2.1 Data ownership & treatment control

Only pharmaceutical companies that own superior clinical data, able to control the treatment process are in a position to predict outcomes and price on that basis.

Data ownership is often less of a problem for pharmaceutical companies in view of the extensive clinical testing of a drug before launch. Not surprisingly, outcomes research, which allows pharmaceutical companies to extend that in depth knowledge beyond the well-defined environment of a clinical trial, has gained a lot of attention recently.

Understanding and especially influencing & controlling the parameters that determine success of treatment, however, is another story. Historically, health care authorities, as well as professionals have been quite reluctant to allow pharmaceutical companies to interfere with treatment practices for obvious reasons. However, the avalanche of web based compliance programmes taking away the heavy burden of following up especially chronic patients from health care professionals is a first step in the right direction.

1.7.2.2 Chronic disease

Secondly, it is obvious that chronic diseases are much more appealing for this kind of pricing model. In case of an acute disease, the value of superior clinical information is only marginal and limited to better drug choice after diagnosis. For a chronic disease, however, small adjustments in the treatment of a patient, such as compliance, can dramatically improve the outcomes and the cost/benefit balance of a treatment.

1.7.2.3 Share of treatment spend

Other critical success factors consist of the size of the market (bigger is better) and the relative share of wallet of the total treatment spent. Players serving a small portion of the total treatment spend are unlikely to have the required data, control or clout to persuade migration to a capitation scheme.

1.7.3 Different types of capitation pricing

Three types of capitation pricing can be distinguished:

<table>
<thead>
<tr>
<th></th>
<th>Product based</th>
<th>Treatment based</th>
<th>Predisposition based</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product based</td>
<td>Price a single product per patient head</td>
<td>Price a complete disease treatment per patient head</td>
<td>Per capita insurance premium that covers treatment cost in case of disease</td>
</tr>
</tbody>
</table>

Figure 1.10: Evolutionary stages of capitation pricing

Pharmaceutical companies have conducted some experiments with product based capitation pricing. Although not always successful, we remain convinced that these initiatives – where successful – will follow a natural evolutionary path towards predisposition-based capitation.
1.7.3.1 Product based capitation pricing
In the first model, the patient will be charged a fixed subscription for the use of a specific drug therapy. This implies that a pharmaceutical company needs to be able to accurately assess the typical cost of its drug product during treatment.

Key requirements for this model are ownership of superior clinical information to assess the right price for drug therapy, but more vitally an adequate amount of control over the treatment.

This model, however, is very hard to price and sell. It would create an enormous burden on customers like hospitals in that they potentially would need to manage a different scheme for each different drug they are using! On the other hand, the added value to the customer is limited.

From the pharmaceutical company’s perspective, control over treatment is unrealistic where co-prescribing is prevalent, undermining one of the critical success factors of an effective capitation pricing scheme. Moreover, competitors would replicate the model as soon as they have reached the same level of maturity in the treatment.

1.7.3.2 Treatment based capitation pricing
To address these constraints and seek a more sustainable source of competitive advantage, we anticipate pharmaceutical companies to experiment and acquire their way into the next evolutionary stage of capitation.

Instead of just a single drug, treatment based capitation covers the complete treatment of the disease in the price charged to the patient. The more complex the disease, i.e., requiring diverse elements for treatment, the more valuable such a package deal will become. Typical examples are the more complex combination therapies like complicated diabetes, cardiovascular diseases and most of the advanced psychiatric therapies.

To successfully operate such a model, it is crucial for pharmaceutical companies to organise themselves around therapy areas. Although pharmaceutical companies do not shy away from this claim, very few actually work this way in practice.

To establish credibility as a one-stop-therapy-shop, pharmaceutical executives will have to pursue strategic mergers, acquisitions and alliances in their effort to gain control over treatment and treatment spend.

The problem with this model is the risk for replication as treatment practices and the knowledge of competitors matures. Therefore, we do not see treatment based capitation pricing as the stable end-state.

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**Figure 1.11: Evolutionary stages of capitation pricing**

<table>
<thead>
<tr>
<th>Product Based</th>
<th>Treatment Based</th>
<th>Predisposition Based</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Multiplicity of capitation providers is a burden to customers</td>
<td>- Replication risk as treatment practices an other player information matures or if has better product</td>
<td>- Future patient is locked before he is even sick</td>
</tr>
<tr>
<td>- Lack of control over treatment</td>
<td>- No significant added value for hospitals</td>
<td></td>
</tr>
<tr>
<td>- Replication risk once another player information matures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- No significant added value for hospitals</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Hard to sell
- Hard to price
- Hard to keep
1.7.3.3 Predisposition based capitation pricing

The ultimate capitation-pricing model is one where a patient does not pay for a drug nor for a treatment bundle, but for an insurance premium covering treatment costs in case of disease.

Pharmaceutical companies that went through the learning curve on treatment-based capitation will have acquired superior knowledge for testing and assessing a patient’s predisposition to disease. Intimacy with treatment control and treatment cost will allow pharmaceutical companies to classify, accept and price disease risks in a way insurance companies can only dream of.

It is not hard to see how a scientific approach to selection and pricing of health risk would be of significant value to life and health insurance companies. Likewise, it is not hard to see how pharmaceutical companies would bend over backwards to lock-in the customer through a health insurance policy, years before that customer may need to be treated.

The strategic rationale for pharmaceutical companies to become health re-insurance providers is very compelling.

A practical problem to making this synergy tale a reality is what we label ‘coverage mismatch’. Health insurers tend to write policies to provide cover for a basket of diseases, whereas even the most broad-based pharmaceutical company is unlikely to support end-to-end treatment of more than a few diseases.

To solve this problem one could envisage an industry platform grouping all treatment based capitation providers, so that the coverage mismatch on an aggregate basis would be minimized. The industry venture would operate as a reinsurance company negotiating health reinsurance treaties with primary underwriters.

1.7.4 First movers

When Florida adopted the most rigorous form a Medicaid formulary in spring 2001, most drug manufacturers responded in the traditional way by promising heavy rebates to ensure their products were accepted in the list. The bloodshed amongst them was significant with Novartis’ Diovan and BMS’ Pravachol among the victims.

Pfizer, however, took a different approach. Instead of cutting prices for its drugs, it proposed state officials to be exempt from such price cuts in return for providing those savings through other means.

Pfizer guaranteed up to $15 million in savings in the first year and $18 million in the second independent of the number of patients entering the programme. If the Medicaid savings fell short, Pfizer accepted to pay the difference.

In order to realize these savings, Pfizer intended to deploy 60 case-manager nurses, using proprietary software to target chronically ill Medicaid recipients. In doing so, it hopes to improve patients’ health and reduce the number of emergency-room visits.

Obviously, other states were watching the experiment closely and another competitor stroke a similar deal with the Florida state officials.

However, this program was discontinued after a few years due to unsatisfying results in terms of absolute savings.

Subsequently, a law was passed barring pharmaceutical companies from offering this program instead of direct price discounts.

Still, Pfizer remains convinced that payers such as insurers, employees and government should focus on managing their overall health-care bill and not just the piece that comes from prescription drugs.

### Figure 1.12: Requirements for each type of capitation pricing

**Product Based**
- **Basic requirements**
  - Superior information
  - Data information systems, e.g. ESAM
  - Influence on treatment:
    - First step with anaemia coordinators
    - Need to transform them into anaemia managers

**Treatment Based**
- **Additional requirements**
  - Carve out product business – done
  - Team up with small player(s) in the franchise that complement your treatment service offering

**Predisposition Based**
- **Additional requirements**
  - Team up with small player(s) active in diagnostic
  - Ally with insurance companies to become a health re-insurer

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1.8 Conclusions and Recommendations

In the advent of launch of a new drug, smart pricing skills are a prerequisite to safeguard blockbuster potential.

The first step in the execution of a smart pricing strategy consists of acquiring a thorough understanding of your product's value. That value is determined by the particular set of product, service and intangible attributes that constitute the three cornerstones of the value triangle attached to your drug. Conjoint analysis can help accurately value each of propositions attributes.

The identification of "the customer" is of prime importance in the assessment of preference profiles and willingness to pay. The forces that act on the buying process to influence the transaction outcome define the customer. Dependent on the case at hand this may be any combination of the patient, health care professionals, health and reimbursement authorities, government & insurers. It is highly likely that the perception of value on your proposition will be completely different for these "customers".

Smart pricing, however, goes beyond finding price against a series of divergent preference profiles. Smart pricing is also about understanding how the various cost containment measures influence the price finding problem. This added layer of complexity can provide a rich source of competitive advantage.

The ultimate winners in the market however are those companies that have conducted some experiments with product based capitation pricing. Although not always successful, we remain convinced that capitation pricing initiatives – where successful – will follow a natural evolutionary path towards predisposition-based capitation. This structure will drive convergence between pharmaceutical companies and health insurance providers.
2 Launch and expansion phase

2.1 Prevalent Strategic Pricing Questions

- At what price should I launch this drug?
- On what basis should I segment the market?
- What pricing strategy should I adopt in the different countries?
- How do I deal with cross-border trade?
- Should I use bundling or other complex pricing schemes
- How can I predict competitor future price launch
- How should I react to branded competitor price moves
2.2 On Customizing Prices

The health care customer is an amorphous entity composed of several stakeholders as seen above. Further more, the health care customer is largely heterogeneous given that drugs are often launched globally, they target various indications and are distributed via different channels. Customers thus differ in the way they are geographically situated, use the product, are subject to various types of constraints, evaluate the risks of switching products (e.g. prefer established to newer products), value different attributes, are informed about alternatives etc. Customer willingness to pay may differ quite significantly across these dimensions.

If the Pharma company were to charge one single price to the various customer segments, it would forego significant profits.

Figure 2.1 shows the consumer surplus that results from a single price in the market versus multiple prices. The more price levels, the more the company will be able to capture consumer surplus. Consumer surplus is the gain to customers that arises from the difference between their personal valuation of the product and the effective price they had to pay to get it. At the limit, if the manufacturer could assess the exact valuation of each customer for the product and charge the exact corresponding price, then the consumer surplus would be all wiped out to the profit of the manufacturer and no money would be left on the table.

In reality, things are not so simple. On one hand, the marketing and sales manager must be able to assign all the various customers into groups that have similar valuation for the drug. The marketer can for example use conjoint analysis to determine these clusters. On the other hand, he or she must be able to maintain a clear separation between these groups so that the high price group is not able to obtain the drug at a lower price. And finally, if the segmentation possibilities are many, he or she must determine the optimal number of groups given the trade-off between customer surplus gain and administrative costs from managing a multiplicity of segments. In summary, the difficulty in customizing prices is three-fold:

1. Distinguish various types/groups of customers who value the product differently;
2. Maintain separation between the groups to be able to charge different prices;
3. Assess the optimal number of groups given the trade-off between value gain and segment management costs.

In subsequent paragraphs, we will discuss the risks and rewards of the various bases for price customization.
Geographical segmentation based on national boundaries is a clear-cut example where the two first conditions for successful segmentation hold. Today, there is a significant spread in prices charged for the same drug across the world as shown in Table 2.1.

The difference in prices stem not only from differences in the manufacturer prices but also from the heterogeneity in wholesale and pharmacy margins as well as differences in VAT.

It is important to note though that the current disparity in manufacturer prices may not be sustainable in the longer run for a variety of reasons.

<table>
<thead>
<tr>
<th>Ranitidine 150 mg (Zantac)</th>
<th>Price Range ($)</th>
<th>Average Price ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OECD countries</td>
<td>75-122</td>
<td>94</td>
</tr>
<tr>
<td>Africa</td>
<td>36-116</td>
<td>75</td>
</tr>
<tr>
<td>Developing countries in Asia</td>
<td>2-61</td>
<td>30</td>
</tr>
<tr>
<td>Latin America</td>
<td>59-94</td>
<td>72</td>
</tr>
</tbody>
</table>

Table 2.1: Comparison of retail prices for Ranitidine across the world

15. European Federation of Pharmaceutical Industries and Associations, 2003
16. H&Lnews Number 112, April/May 2000
With the Internet, the revolution in information and communication has resulted in increased price transparency and globalization of procurement. In Europe, the arrival of the Euro currency in conjunction with short / medium travelling distances – and accordingly limited transport costs – between countries intensifies the threat. Parallel trade threatens to break the long-held national boundaries. Effective price differentiation may only be maintained so long as the price difference outweighs the transaction costs associated with the set-up and operation of a parallel importation activity. The volume of cross-border trade and the number of parallel importers involved has significantly increased in the last 2, 3 years. Choice of distribution channels for the drug may be crucial as it determines the access of third parties to the product via wholesalers. Direct distribution to retailers or points of care reduces intermediaries and thus reduces potential for parallel trade.

Finally the benchmarking practiced by health authorities in some European countries (e.g. Greece) to determine reimbursement prices as well as EMEA continuing efforts to standardize regulations across Europe will lead in the longer run to a levelling of prices.

**Figure 2.3: Drug distribution flows in Europe**
Distribution channels could also be a basis for customer segmentation if drug distribution is not done via common wholesalers who provide both retail and hospital markets i.e. a wall between retail pharmacies and hospital pharmacies is maintained. Figure 2.3 shows that in Europe drugs are typically distributed directly to hospitals rather than passed via a wholesaler. Hospitals, clinics and health maintenance organizations that purchase drugs directly from manufacturers and influence the prescribing practices of doctors frequently pay much less for the same product than retail pharmacies. Budget constraints under which these hospitals and clinics typically operate make them highly price sensitive. Moreover concentration increases their bargaining power: the more influence the purchaser wields in its ability to favour one brand-name drug over a similar competing drug, the higher the discounts and rebates can be. Note that health care companies are quite often willing to provide these discounts in hospitals given the likeliness of «drug initiation effect» once the patient is out of hospital and back to the community.

Segmentation by indication is another possible avenue. It is typically more complicated to apply because the segments are well defined but it is pretty difficult to avoid migration between the various indications. Health authorities typically do not grant different reimbursement prices for the same drug even if it is used in multiple indications. Hospitals have typically one procurement centre and refuse to pay different prices for the same drug even if it treats different diseases.

Drugs typically come in various presentations. Pills, syringes, syrups, all come in various shapes and sizes. An important question faced by marketers is how to price the various presentations.

Non-linear prices for different put-ups may be a basis for segmentation across indications – as different putups «naturally» fit different indications – but can also create risks of re-titration and repackaging. Whatever pricing strategy is applied, it is essential to have a coherent clinical justification for the price differences.

Creativity is needed to be able to segment customers by indication. The use, for instance, of a different presentation for each indication, playing on dosage, administration frequency and administration mean (IV, SC, IM, inhalation). There are of course risks of re-titration and repackaging across indications. Timing the launch of the various indications can be critical in that regard where the launch of the less price-sensitive indications should take place first. Other possibilities exist, like providing value-added services to the customer via patient programmes, treatment databases for the physicians, or bundling the drug with other indication-specific drugs.

The next section addresses bundling as well as other similar complex pricing structures.
2.3 What About Complex Pricing Structures?

If market segmentation is difficult to implement, it might be possible instead to offer various price propositions and let the customer self-select the option they value most. We thus start using more complex pricing schemes.

A complex price scheme could serve various purposes. It increases profits compared to a simple linear pricing. It can be a way of countering the increased transparency by making price comparison with competitors difficult. Complex price schemes also raise the barriers that users must overcome to change from one product to a competitor product by increasing switching costs.

Imaginative marketers have devised a multiplicity of complex pricing schemes. However diverse they look, the schemes typically used to price drugs belong to a few categories.

**Volume-based pricing** is widely used and takes the form of incremental quantity discounts, loyalty programs, year-end customer bonuses and other similar schemes. They are used to decrease price transparency as well as reduce customer incentive to switch to other products.

**Bundled pricing** is another complex pricing scheme where two complementary products are priced together in a bundle, which makes it difficult for the customer to determine the effective price for each and thus make price comparison to competitors less transparent. Bundling may be used to push and support one drug, using the market success and notoriety of another drug it is bundled with and thus increasing overall profit for both products.

The example in Figure 2.4 illustrates pricing choices for two alternative strategies: sell the drug X in isolation or bundled with another drug Y. The manufacturer has an objective of profit maximization. P2 represents the price that maximizes profit in each market alone while P1 is the price that maximizes the profit in the bundled market for both drugs. When setting a bundled price P1, the manufacturer sells volume Q_d1 of Drug X and increases the volume of drug Y sale from Q_d2 to Q_d1. In this particular example, a bundling strategy between the two drugs would be meaningful as the profit is higher across the combined two drug markets than for every market in isolation.

In practice though, bundling is difficult to implement especially in the retail sector due to legal restrictions. More opportunities are available in hospitals and clinics where a manufacturer may be able to sell several products together on the basis of an overall volume discount.

Figure 2.4: Bundling is preferred if area B is larger than area A.
2.4 When Competitors Start Interacting

Up to this point, dynamic interactions with competitors, were somehow left out of the picture or rather the competitors were assumed to be in a given – static – position. It is clear that the «ceteris paribus» status does not hold in real life.

Both you and your competitors react to external market influences and internal constraints. You both try to anticipate what the other will do. The winner recognizes this fact and incorporates it in his strategy! With the introduction of other stakeholders’ reactions and the need to anticipate several steps ahead, we start playing chess for real.

The question is where do we start and how do we proceed when there are so many stakeholders, such a large spectrum of possible reactions and multiple time periods where encounters happen repeatedly.

Game theory (GT) can help answer these questions. The different decision-makers interact in a game so that the actions of each one influence the outcome for all. GT helps in particular to analyze a given market, anticipate competitor moves and influence their actions.

So what is new here and how is this any different from just using common business sense? Well, as seen above, most problems are too complicated and we typically have too much information. GT helps you shed the excess details to reach the core of the problem; it proposes ways of simplifying decision problems.

In short, you set up the problem by answering a series of questions on the players, their objectives, their strategies, their constraints, their culture, their values and the order of the main decisions in the market that you need to analyze. You then model the decisions by starting with a limited number of choices (e.g.: set launch price High versus Low; React to competitor move Aggressively versus Moderately; Tighten reimbursement rules Yes versus No etc.) and drawing the corresponding tree.

At the end of every branch of the tree, the payoff for each player is put. By recursively solving the tree the optimal and most likely actions for each player can be identified to unveil your optimal strategy.

2.4.1 Likely behavior of competitors in the market

Game theory may be applied to analyze the incentive for friendly behavior of various players in a given market. We dubbed this technique competitive behavioral analysis. Even in its simplest 5-question form it awards significant insight in likely competitive pricing behavior.

As the number of players increase, the dynamics in the market change significantly, the complexity of coordination increases and asymmetries between players increase making achievement of an equilibrium price more difficult.

A player may have various objectives. Profit is an obvious one, but it may alternatively be revenue and market share. It may also be other strategic objectives like for instance striving for strength in one therapy area by broadening the portfolio of products or having a stream of replacement products, or using presence in one therapy area to maximise presence in another.

Who are the players? Your company, Your main competitor(s) which ones really matter for your business? Potential new entrants to the industry; Regulators? Customers? Are they trying to anticipate your actions? Or are they just responding passively to them?

What are their objectives? Profits? Sales / market share growth? Brand recognition? Anything else?

What strategic choices can they make? Pricing aggressive or accommodating? Product quality high or low? Service competition, Research and development, Investment in branding (advertising, product bundling…), Organizational changes (mergers & acquisitions, joint ventures…)

Under what constraints are they operating? Constraints general to your industry cost structures. Importance of intellectual property? Constraints specific to your problem, capacity constraints, existing brand loyalties, patent expiry, organization of purchasing decisions, etc.

What is the order of the main decisions? You move first, it’s your decision you are trying to analyse. Who moves next? Whose next decision do you really care about? Call this player 2. Whose subsequent decisions will player 2 most care about? Call this player 3. Three players are enough to start with.

Table 2.2: The five main questions for any business problem (Source: Paul Seabright «Game Theory: a tool for business strategy»)
A player’s objective is important because it determines the optimal price for that player. If all the players’ objectives are the same, it facilitates a congruent perception of the optimal price, which leads to price stability.

Assessing the player’s objective is also fundamental to understand what indicator the player would be monitoring.

If you were targeting market share for instance, you would set up a price $P’$ lower than $P$ which is optimal if you were targeting profit as illustrated in Figure 2.5.

A player’s strategy determines the way a player chooses to realize his objective. To reinforce your presence in a market, you may choose different strategies. You may use for instance differentiation via product specificity and presentation variety. Alternatively, you may use bundling of two complementary products for the treatment of a given disease to facilitate procurement for points of care. You may also choose to strengthen brand loyalty via marketing and other initiatives.

Competitors typically operate under a series of constraints. Gathering information on your competitor constraints is highly tactical as it allows you to determine what your competitor may or may not do. Typically the more constrained a player is, the less likely he is to pursue an unfriendly pricing strategy.

We believe that the following four constraints are particularly crucial to the competitive game:

1. Supply chain cost
2. Spare capacity
3. Information availability
4. Values and beliefs of the company

Differences in supply chain costs lead to different optimal prices. The lower the variable cost, the lower the optimal price. The competitor with the lowest variable cost has an incentive to pursue a price cutting strategy to gain extra volume. This will lead to unfriendly behavior in the market. The more price sensitive the market is, the greater the pay-off for a price cut strategy. Price stability in a market where players have different variable costs is difficult to achieve.

In Figure 2.6, the two competitors have different variable costs $VC_1$ and $VC_2$. The prices at which each competitor maximizes profit are different: $P_1$ for competitor 1 and $P_2$ for competitor 2. Competitor 2 with the lower costs has more incentive to cut prices.

The amount of spare capacity limits the possibility to exploit price cuts. The player with the biggest spare capacity has the greatest incentive to drop price in order to utilise spare capacity. While a player with no spare capacity cannot make a credible retaliation threat because he is unable to supply the additional volume required.

Lack of information or delays in receiving that information reduce the responsiveness to retaliate and thus increase the pay-off for the player who breaks the friendly behavior game. In addition, poor quality information may lead to incorrect conclusions regarding competitor behavior and cause the implementation of inappropriate countering strategies.

The cultures and values held by the competitors may explain seemingly irrational behavior. Understanding them can therefore help in predicting a player’s possible irrational behavior.
2.4.2 Pricing policy reflects player’s characteristics

A very important output of the competitive behavioral analysis is the likely pricing policies for the competitors. The pricing policy is the rule that the company will follow to change its own prices when faced by changes from its competitors. The notion clearly includes dynamic aspects, as the rule will apply repetitively for a given period of time.

A player’s objective and strategy determine the nature of the pricing policy the player uses, while the constraints, cultures and values determine how the policy will be used.

There are 3 main elements that define a pricing policy:

1. The information on which the pricing policy is based: this can be one of two parameters: competitor price or own market share.
2. The speed of response: a tolerant player will not make a move unless there is a significant gap between current versus targeted/acceptable levels. Tolerance may be with regards to price gaps or market share drifts.
3. The friendliness of response: a player may choose to partially make up the difference between his own price and that of his competitor (Accommodate), fully make up the difference (Match) or establish a difference in his favour (Punish).

The ability to identify minor deviations in competitor price or own market share depends on a player’s ability to monitor the environment. A player who cannot measure performance in a timely way is unable to assess the situation accurately and react appropriately.

The level of friendliness/aggressiveness of a new player is reflected in the launch price. A player with a high incentive for aggressive behavior is likely to launch at a lower price, be less tolerant and therefore retaliate quickly.

The policy assigned to each of the players is an educated assessment based on the competitor behavioral analysis that has been carried out. Obtaining updated information on the actual pricing policy adopted by other players prior to and post any new launch will be necessary to ensure that the pricing policy is relevant to the market conditions. Certain indicators can of course help to identify the pricing policy that a player has in place. Obviously the launch price level is one of these indicators in the case of a new product, but you may also monitor the speed of retaliations as well as the magnitude of retaliations.

The success in adjusting the pricing policy hinges on the organisation’s ability to develop excellence in market and competitive intelligence. Various software packages17 are available to support that competitive intelligence effort. Monitoring the indicators and interpreting them is the crucial first step. Each pricing round should be analysed so that the learning points can be identified. The product pricing policy should then be adapted to any new market conditions for example, by changing the nature of the pricing policy or the speed of the retaliation.

2.5 Into the Realm of Market Dynamics

Having parameterised the competitive characteristics of the various players and assessed their likely pricing policy, it is now time to model market dynamics.

The feedbacks between competitors and market on the one hand and the non-linear and often complex dynamics on the other hand must be accurately represented. For this purpose, we use the System Dynamics modelling.

Once the model is built, model simulations allow us to compute the expected net present value of the life cycle profit for each competitor under the various scenarios. These figures are then fed into the Game tree to complete the overall outcome analysis.

2.5.1 About system dynamics

System dynamics is a method to enhance learning in complex social systems and thus deals with policy resistance, counterintuitive behavior of social systems and law of unintended consequences.

Jay Forrester developed the method at MIT in the 1950s and the result is fundamentally interdisciplinary. Grounded – from a technical point of view – in the theory of non-linear dynamics and feedback control in mathematics, physics and engineering but applied to real-life problems and thus drawing on various social sciences like social psychology and economics.

The driving motto of systems dynamics is the recognition that the world is a complex system in which any action on our part creates ripples that are fed back to us in unexpected ways and often with delays. To be able to better assess the impact of our actions, we need to model a virtual world that encompasses all the relevant influences and links and where the main interactions and feedbacks are represented dynamically. Running simulations in this virtual world will allow us to learn about the true world and to take the actions that will favour overall longrun objective in contrast to short-run objectives. This is the objective of system dynamics.

Various software packages exist to help with the representation and modelling of the situation of interest, the main ones being Ithink™, Powersim™ and Vensim™. A powerful advantage of these packages consists in having the mathematical equations directly hidden behind the graphical representation. It is thus possible to keep an overview of the model via the diagrammatical representation and operate changes to the model structure with significant flexibility and speed. This also makes it much easier to communicate the model in general and explain its basic structure.

Let us look more closely at a possible model structure for competitive pricing strategy formulation. Modular in nature the structure would typically represent the pricing policy of the competitors, the market share adjustments, the market size and growth and also the resulting life cycle payoff elements that summarise the outcome for each competitor.

The dynamics unfold as follows: we start from the current market situation (initial values in the model) with a given number of patients [market size] that are served by the competitors in specified proportions [market shares] given the value proposition of these competitors (in particular given the current net effective price levels charged). As long as nothing new happens, the initial equilibrium is maintained and the growth of the market is shared in the same initial proportion between all competitors. Interesting reactions start to appear when a new product is launched in this market or when a current competitor initiates an aggressive move. Pricing policy derived from the competitive behavioral analysis will dictate how and when each player changes price. Customer price sensitivity, as determined by the conjoint analysis, will dictate how the market shares change in reaction to price changes with of course adequate delays introduced to reflect the particular sluggishness of the analysed market. Changes in market share might induce other price changes until a new equilibrium is reached.

In each period of the model (quarter, month, week etc...), profits are computed for each competitor on the basis of their current price, volume and variable cost. The cost of capital discounts future profits and overall life cycle profit is computed for each competitor.
2.5.2 Building blocks in the dynamic pricing model

To link the modules in figure 3.11, various building blocks are needed. In the following section we describe a few essential ones. When presented with competitive alternatives, the customer perceives the complete value proposition covering all elements of the value triangle. We need some way to reflect the elements in a one-dimensional measure. This is the notion of value parity price ratio.

2.5.2.1 Value parity price

Value parity price ratio is the relative price that represents the average perceived value of all customers for the new product value proposition versus the incumbent value proposition. An average buyer is indifferent between the two competitive products at value parity price ratio, i.e., value parity price does not help nor restrain the uptake of the competitive product versus the reference product for that average buyer.

Figure 2.8: Customers perceived value of new drug relative to incumbent drug.

Consider a given product on the market with a given price and a given value proposition. A new product is to be launched with another value proposition. Each customer has his own perception on what the value is of the new product to the incumbent product. Taking each customer's perception into account, an average value for all customers is derived: it is the value parity price ratio and in our example it is equal to 1.10. Then if the new product is priced at 10% premium, the average customer – Customer B in Figure 2.8 – will consider this as fair pricing and will be indifferent between the two products i.e. equal chances to switch or not, given on one side the natural curiosity towards a new product and on the other side the potential hassles from switching products. Customers to the right of B, who value the new product by relatively more than 10%, will all switch, while customers to the left of B who value the new product by relatively less than 10%, will continue to buy the incumbent product.

2.5.2.2 Cross elasticity

Cross elasticity of the market indicates how sensitive the purchasers are to a difference in price between competitive products. Cross elasticity is typically determined from a conjoint analysis market study.

Figure 2.8 illustrates a typical cross elasticity curve. The S-curve shape reflects a normal distribution of prescribers' opinions around the price ratio that establishes value parity. Switching costs justify the relatively flat area around value parity price ratio: purchasers would not typically switch products readily if price differences are limited within a 2% to 5% interval.

2.5.2.3 Market price elasticity

Another important assumption relates to the market price elasticity. Market elasticity is the sensitivity of the market potential to overall price level. We need to assess whether a price reduction might add to the «organic» market growth and quantify that impact.

We might predict that if prices drop on average to 80% of initial levels, the market will grow by an extra 5% to what was originally foreseen. The growth of the diagnosed patient population determines the original «organic» growth forecasts while the extra growth would be due to an increased penetration of the treatment (more diagnosed patients who receive the treatment)

2.5.2.4 Evolution of competitor market shares

Market shares are likely to evolve when price changes are first implemented and potentially followed by retaliatory pricing actions. When a new product is launched at Value Parity price ratio, it acquires gradually a given «natural» market over a predetermined period of time. The natural market share may be determined through conjoint analysis. If the new product is launched at a premium or discount to Value Parity, then the cross-elasticity will determine the appropriate market share to be deducted from or added to the «natural» share. In a stabilised market, a price cut left unmatched by another player will lead to decay of market share over time. This decay is driven by the cross-elasticity curve based on the changed price ratio. Restoring the price ratio to its previous value allows a player to stop the loss of further market share but not to regain lost market share. This is justified by the existence of switching costs and a natural reluctance to change that inhibits the take-up of previously lost market share. To regain market share, a player would typically need to undercut the competitor's price.
2.5.3 Unfolding the chess game

Let’s finally illustrate how – once your problem is set and you have obtained the various possible outcomes from the model simulations – you may finally analyze the game tree to assess most likely overall outcome.

To that purpose we use a simple example adapted from the famous Prisoner Dilemma case. Consider a stable market equally shared between two manufacturers, Alpha and Omega. Both players have as long-run objective to maximise life cycle profits, both use pure pricing strategy and operate under similar constraints. Alpha is under pressure from its corporate headquarters to increase sales and Omega is aware of the threat as it has noticed lately some aggressive signs from its competitor in the formerly stable market. Omega is wondering how to react to this potential threat i.e. what would be the best strategy to adopt in case Alpha indeed starts cutting prices. Moreover, Omega is wondering whether he should not be pre-empting Alpha’s move and lowering its own prices.

So what is the most likely outcome for this highly fused – and unfortunately too often familiar – situation?

![Figure 2.9: Game tree output](image)

The numbers in Figure 2.9 describe the outcomes – life cycle profits in billion Euros – under the given decisions as computed in the dynamic pricing model simulations.

Consider the situation from the point of view of Omega. He asks himself: «what is Alpha likely to do?» There are two major strategies for Alpha: «Cut Price» or «Hold Price». Looking at the possible outcomes, Omega realises that Alpha will always be better off cutting price whatever Omega does. Knowing this, Omega is also better off cutting price. This leads to a vicious circle in which the prices spiral downwards. Individually therefore each player has an incentive to cut price but this is not the optimal solution. Collectively both players are better off holding price.

Game trees and system dynamics form a very powerful bundle to analyze competitive pricing strategy. It’s like playing out an entire game of chess before you have moved your first pawn forward.

The key question is therefore: «How is it possible to actively manage the stability of the co-operative outcome – where both players have a life cycle profit of 4 billion Euro – and discourage price-cutting?»

There are in fact a variety of options that help in managing the stability of the co-operative outcome. These price protection strategies will be further explored in section 4.
2.6 Conclusions and Recommendations

We have presented in this section a series of tools that support pharmaceutical company executives in defining an optimal pricing strategy for their product during launch and expansion phases. The proposed approach is summarised in Figure 2.10.

Figure 2.10: How to build and optimal dynamic pricing strategy for your product.

The next section will address in more details the maturity and decline phase in the life cycle of a drug.
3 Maturity and Decline Phase

In a mature market, a product typically faces more than one ethical drug competitor. Moreover, the generics threat nearing patent expiry only increases the competitive pressure. What avenues are open to a pharmaceutical company to cope with these issues and cut the often vicious price spiral?

3.1 Prevalent Strategic Pricing Questions

- How can I shift the focus away from price?
- How do I adapt my product proposition to maintain sales?
- What is my price setting against generic products?
- What other defence strategies are viable against generics at patent expiry?
- What options should I take anticipating the end of life cycle: strategic alliance, harvesting, retrenchment ...
3.2 Proactive Pricing Strategy

Proactive strategies focus on both customers and competitors and refer to all types of actions – other than pure pricing – that can be taken to protect the life cycle profit of the product. The intention is essentially to move the focus away from price and to reduce price cut incentives in the market.

3.2.1 Creating differential value

Differential value is created around a product in order to distinguish it from competitive offerings. This difference must be of real value to the customer. Differentiated products and services are more difficult to compare like-for-like in the eyes of the customer. Two factors will contribute largely to the success of the differentiation strategy:

1. The perceived differential value must be higher to the customer than the monetary value to create it
2. The differentiation must be sustainable

Generally, three main types of differentiation can be considered:

1. Product differentiation
2. Service differentiation
3. Channel differentiation

3.2.1.1 Product differentiation

You can differentiate from your competitors by building on new formulations or multiplicity of presentations. Typical examples are the launch of long acting or inhaled versions of existing drugs. Similarly, all sorts of devices that facilitate drug administration are a common way of establishing a competitive advantage although often short-lived as competitors tend to replicate it.

Diabetes is the exponent of a market in which product differentiation is the prime strategy to build a competitive advantage. Product differentiation has led to the development of a whole range of devices & formulations that make life easier for the patient. Typical examples are Novo Nordisk’s NovoPen®-3 for easier and less painful insulin administration, the long- and short-acting insulin analogues. That not all these differentiations necessarily create value can be demonstrated by the inhaled insulin formulation, Exubera. The formulation was developed by Inhale Therapeutics and licensed to Aventis/Pfizer. Despite energetic launch efforts, it was discontinued in 2007 due to high costs and weak sales.

3.2.1.2 Service differentiation

Providing value added services to a product is a strategy that most ethical drug manufacturers typically pursue. Examples are many like providing funding for nurses in hospitals, for call centre support or the provision of educational and training programmes for health care professionals through sales reps or nurses. The more the service is unique and adequate to the real needs of the customer, the higher its perceived value.

The drawback with this approach, however, is that the service is not always adequately accounted for during the decision making process. This could be the case for a variety of reasons. Either because the service is of value to a limited part of the decision makers. For example, some pharmaceuticals companies have developed a competitive advantage in the past by providing high quality services to the health care professionals. During the tender procedures in hospitals though, physicians have only limited decision power while the head pharmacist who has major influence cares about cost arguments rather than service elements. Alternatively, not accounting for the service could be due to the fact that the service value falls under another budget than drugs. Again in the hospitals example, a pharmacist responsible for the drug budget would not be overly interested in a service offering of free nurses that would benefit some other hospital budget.

This type of situation is exactly what pharmaceuticals companies focusing on this type of differentiation are facing in the UK currently. Needless to say that it is imperative that this situation be changed to have such service offering officially accounted for in tenders. Otherwise the cost of such services to the pharmaceuticals company will outweigh the benefits – in product differentiation, account management etc.– and the pharmaceutical companies may decide to stop providing them with the expected negative consequences on the quality of health care.

3.2.1.3 Channel differentiation

Utilising the sales channel can be highly attractive in that it allows you to get more intimate with the end-user thereby improving your insights in the buying decision process. Unique options may be pursued which are often difficult for competitors to mimic.

One example is supplying just-in-time to distributors and reducing their stock holding. This benefits both distribution management and manufacturing by gaining access to more accurate and timely sales data. Direct distribution to points of care is another less commonly known example. With wider access to the Internet, other channel opportunities are emerging as well.
When Actelion, a Swiss based biopharmaceutical company, got approval for its pulmonary hypertension drug Tracleer in November 2001, it announced that it was setting up a closed distribution system for the drug. Only patients on the «Tracleer Access Program» will be able to receive the drug therapy & the product will not be available through normal distribution channels. System pharmacies will deliver the drug once a month to the patient & Actelion has contracted a company to take care of reimbursement & coordination of the distribution programme. The delivery will include a medication guide and a reminder card for some screening tests. The pharmacies will also call each patient monthly to inquire about the tests, but delivery of Tracleer will proceed irrespective of the patient’s answer. However, in case the patient responds «no» to the questions, the prescriber will be contacted to determine the reasons for the lack of compliance. EU wide marketing was granted in 2002.

3.2.2 Influencing competitive behavior

Proactive strategies may also be used to influence competitor behavior in order to increase the likelihood of other players adopting more friendly and constructive behavior in the market. Several avenues are open to reach such a result even if they are not always easy to implement.

3.2.2.1 Growing the market

Growing the market is desirable as the pioneering pharmaceutical companies are likely to benefit most from the increase in demand, at least for a certain time. The focus is on acquiring new business rather than stealing competitors’ business as competitive fierceness is likely to decrease in a growing market where there is more business to share around. Growth can be achieved through acquiring new customers or finding new segments. The most obvious way of putting such a strategy into practice is the exploration of new therapeutic indications for a drug. Often new niche markets are less informed about products and price and may be prepared to pay a higher price. Market development by the pharmaceutical company also signals to customers that the company is actively investing in the product and thus creates goodwill.

The limitation of that strategy is obvious: competitors with strong marketing capabilities are likely to catch on quickly in the new segments without having to bear the investment cost so the pioneer company would be in fact priming the market for followers.

3.2.2.2 Cross-retaliation threat

Building a cross-retaliation threat can be a very effective way to bring peace, be it armed peace, to the market.

Cross-retaliation threats are most effective when created in an important market (cash cow) for the competitors. This means in practice that if your competitor behaves aggressively in the market where you are dominant and thus have everything to lose, he might risk seeing you reproduce his own behavior in another market (the cross-retaliation market) where you are dominant and thus has everything to lose. Another market may be anything from another geographical region to another product. A cross-retaliation threat towards most aggressive competitors can be very effective in stalling price cut moves, but it is not always naturally available. Significant efforts and advance planning are often needed to build it via alliances and/or acquisitions that would challenge your competitor where it hurts the most.

3.2.2.3 Strategic alliances

Building an alliance aims to achieve an agreement that is synergistic and mutually beneficial to both parties. Alliances may be arranged quite early on in the product life cycle – in the launch and expansion phase – as well as at later stages when maturity sets. Alliances may be arranged with one or more than one partners, and the various types include such options as co-marketing, acquisition or licensing agreements.

For example, a company may decide to buy-out unused capacity in order to achieve a more similar capacity utilisation among players. This will put players on the same footing and decrease the incentives for price-cuts.

Another example is in licensing agreements where structure and basis of royalty schemes drive the incentive for friendly behavior. For flat fee royalties, there are incentives to reduce price for a higher volume. Percentage royalties based on sales value create some incentive to reduce the price as part of the price cut is shared with the other party. Percentage royalties based on sales volume create no incentive to reduce price and is most likely to induce friendly behavior in the market.

3.2.2.4 Communication

Communication to the market can help increase co-operation incentives and advance «pricing IQ» of the market. You could for example, publish a market elasticity study in order to adjust other players’ perceptions on price sensitivity. You could also communicate your own differentiation strategy and endorse the differentiation position of your competitors. Taken to the limit, you could even consider publishing your pricing intentions, price lists and pricing policies.

19. Needless to say that pharmaceuticals companies must use every caution to ensure that none of these strategies may be criticised by authorities as anti-competitive or collusion behavior.
3.3 Generic Defence Strategies

Even though patent grants in the pharmaceutical sector may be up to 20 years, the effective patent life is noticeably shorter given that patents are filed at early stages in the drug development and the resulting erosion of branded product sales. As a result, a wide range of strategies has been developed by pharmaceutical companies to defend their products after patent expiry.

«Although the cost of developing drugs is soaring, the time that companies have to recoup their investment is shrinking because of stepped-up competition from generic drugs.»

Broadly generic defence strategies can be classified into product variety defence and legal defence.

3.3.1 Playing on product variety

In the product related defence, the pharmaceuticals company can either play on variations to the current drug with indication extension, line extension, multiplication of presentations, etc.. Or it can build on second and third generation drugs with improved value to the customers. Timing is of essence, as the company needs to transfer as many customers as possible to the new product or presentation prior to patent expiration.

Eli Lilly’s has reinvested in research for its star product Prozac (fluoxetine) in 1996 i.e. five years before patent expiration, and came out with two new developments. A new indication for pre-menstrual dysphonic disorder approved in 2000 and marketed as Sarafem and a once-weekly formulation for depression approved in early 2001. With these launches, Eli Lilly managed to partially offset the strong sales decline (65%) of Prozac after patent expiration and survive as an organisation. Anno 2009 Lilly is among the leading innovation-driven pharmaceutical companies with a strong pipeline in cancer, multiple sclerosis, diabetes, osteoporosis, rheumatoid arthritis and Alzheimer’s.

In a pre-emptive move to switch as much patients currently on Claritin to its second generation drug Clarinex, Schering-Plough launched its new anti-allergy drug at an 18% discount compared to its blockbuster drug which came off patent end 2002 20.

3.3.2 Using the legal arsenal

Legal challenges comprise a series of tools. Patent defence in court is based on one or several of the patent types. The strongest claim is via composition of matter patent, followed by process patent and finally method of use patent. Litigation over patents can take years to settle and no generic manufacturer can enter the market during that time.

Lobbying with health care and political authorities is also used by pharmaceutical companies to extend where possible the period of market exclusivity for their drug. Lately, a lot of lobbying is conducted around biotech drugs. For chemical drugs, generic companies have typically a huge advantage over branded manufacturers as it suffices for them to show bio-equivalence to the branded product to be exempted from any clinical trials showing efficacy and safety of their product. With biotech drugs, the issue is being raised all over again as bio-equivalence is much harder to prove and safety is a big issue for every batch. Branded manufacturers are currently lobbying health authorities so that biotech generic manufacturers be required to provide clinical data evidence proving the safety and efficacy of their product. If it passes, this will of course significantly hinder any but the largest generic manufacturer to enter the market and will also probably delay entrance for the largest ones.

The pharmaceutical manufacturer must nevertheless be discriminative in using legal litigations as certain legal loopholes may be financially rewarding but may also risk injuring their reputation and relationship with public authorities and, even worse, generate negative press coverage.

Bristol-Myers Squibb has used a legal loophole for its anti-anxiety drug Buspar (buspirone) by presenting to FDA in November 2000 – a few hours before patent expiry- a new patent covering one of the drug’s active metabolites. Although the validity of the submission was questioned, the FDA had to deny other applications for marketing generic buspirone. Generic manufacturers sued BMS and eventually won the right to sell generic buspirone but in the meantime BMS had ensured itself an additional five months of market exclusivity.

20. Reuters, 27 December 2001
3.4 About Final Options

The end of life for a drug may come in various forms but it is typically related to one of two types of event: end of patent and dangerous side effect revealed by post marketing surveillance.

In rare unlucky cases, post marketing surveillance might reveal a major side effect to the drug. This would lead to two alternatives: either discontinue the drug on a permanent basis for security reasons or discontinue it temporarily and run further trials to try to salvage something out.

Fortunately, a more likely case is to see the product reach its end of patent deadline without such dramatic events. Several options are open to the pharmaceuticals company:

1. **Business (almost) as usual:** This option applies in particular in the case where generics are kept out of the market even after patent expiration using some of the means described in the previous section. This strategy is often executed in conjunction with a channel strategy (typically to OTC) to further raise barriers to entry.

2. **Generic Branding:** Several pharmaceutical manufacturers like Novartis and Merck, have chosen to go for the generic business to protect their marketing and manufacturing investment in the branded drugs. The expertise to successfully run a generic company is very different from the one required in a branded business and nowadays most of these generic extensions take the form of an alliance or partnership with a generic manufacturer rather than an acquisition or the creation of a generic subsidiary.

3. **Harvesting:** Stop investments in sales support and brand building to initiate harvesting the product. Once all your options to delay generics at the end-of-life of the product fail, you could just chose to sub-contract manufacturing of the product and just harvest whatever profit is left from customers who highly value your product brand and are ready to pay for it. Needless to say that following the generics on a price discount course is not the way to go. Rather stick with your higher price level and sell to the few faithful customers who are willing to pay a significant premium for your brand.

4. **Retrenchment:** Divest and concentrate on something else.
3.5 Conclusions and Recommendations

The maturity and decline phase is a difficult phase to manage from a pricing angle as the market excitement over the new product ebbs while the number of competitors increases.

To manage price protection under maturity, a series of proactive pricing strategies can be pursued to shift customer focus away from price. Furthermore, several (legal) generic defence options may be considered to protect against generic entrants.

To manage your offering under decline, Business as usual, generic branding, harvesting and retrenchment should be considered.
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Authors

Wouter van der Meer

Wouter, lead-author of this paper, is a partner with Infosys Lodestone and responsible for its Strategy and Business Process Consulting practice. He specializes in Corporate, Market and Pricing Strategy and holds an MBA.

Jan Kerkhofs

Jan, researcher for this paper, is a senior consultant with Infosys Lodestone and is part of the Strategy and Business Process Consulting practice. He specializes in Business Modelling.

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