TOWARDS A CONSTRUCTIVE DIALOGUE ON PHARMACEUTICAL PRICING

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WHAT DRIVES US

There is still a lot of unmet medical need that requires the combined effort and support of all stakeholders to develop new breakthrough therapies. At the same time the system needs to be affordable, to remain accessible to all patients. At Vintura, we believe this is possible, but will require a new way of working.

Vintura's mission is:

'Creating meaningful impact in healthcare together'

Stakeholders have to work together in order to find real solutions and to ensure patients have access to the best possible therapies for a fair price for all stakeholders. Therefore, we seek to align stakeholders in healthcare to improve the healthcare system in a sustainable way.

With this paper we aspire to contribute to this stakeholder collaboration and further the progress towards our mission.

ABOUT VINTURA

Vintura is a leading consultancy company dedicated to improving healthcare. We support hospitals, the pharma industry and the medical devices sector. Our team of over 25 highly skilled consultants has extensive industry knowledge and expertise. Our experience in international markets allows us to support clients across Europe and beyond. The firm was founded in 2000, and since then we have been supporting our clients with their strategic and organizational challenges and changes.

INNOVATIVE THERAPIES RADICALLY CHANGED OUR LIVES

"I should have been dead by now," says 64-year-old Judith from the Netherlands," "but I'm still able to do a lot of things and am still having a lot of fun. These medicines mean a lot to me and to others as well." Having been diagnosed with cancer in her right lung in 2004, Judith survived because of a successful chemotherapy and radiation therapy. These therapies then went on to save her again when the cancer returned, this time in her left lung in 2010. But after that, too much damage had been done to her body to continue using these therapies. She was lucky to be selected for a drug trial. The innovative drug being tested, which stimulates her immune system to attack the cancer cells, has significantly reduced the spreading of cancer cells and is now keeping her alive.[i] Had Judith become ill 15 years earlier, she would most likely not be alive today.

This example shows how innovative therapies have radically changed the lives of millions of people in Europe and across the world (see also Box 1). People live longer and healthier, regain their freedom, can go back to work, have less pain and their quality of life has improved significantly.

BOX 1: INNOVATIVE THERAPIES ARE THE GREATEST CONTRIBUTOR TO RECENT INCREASES IN LIFE EXPECTANCY

- In the Netherlands the overall 5-year survival rate for people diagnosed with cancer has increased from 47% to 62% in the period 2008-2012 compared to the period 1989 – 1993. [ii]
- In the OECD countries life expectancy at birth increased with 1.74 years between 2000 and 2009; innovative therapies accounted for 73% of this increase. [iii]

TOWARDS A CONSTRUCTIVE DIALOGUE ON PHARMACEUTICAL PRICING

1. In the US, costs of cancer gene therapies are expected to increase by 20.7% per year, reaching a total of over 1.2 billion USD by 2024. [iv]

2. However, contrary to common perception, per-capita pharmaceutical expenditure in the European Union increased by only 1.3% per year between 2010 and 2015. [v]

The price of innovative therapies is subject of a heated debate, in which payers and pharmaceutical companies find themselves in opposing positions on what constitutes a 'fair' price. What manufacturers consider 'fair' is not what payers consider to be 'fair', and vice versa. The opposition becomes fiercer as populations are ageing, more innovative and personalised therapies are becoming available[1], and the sustainability of healthcare budgets is being compromised.[2] This may cause patients to be affected by restrictions on the use of newly launched therapies.

A constructive dialogue is urgently needed to find pricing solutions that balance the needs of pharmaceutical companies, payers and society. Currently, there seems to be little room for nuance, recognition of each other's needs or a joint quest for win-win solutions. We argue that four questions should guide the assessment of a new therapy:

1. What constitutes value?
2. What are pricing criteria?
3. What is the price dynamic?
4. How are risks shared and payments made?

In this paper, we offer a framework for a step-by-step assessment of each of these four questions. This framework can support a structured dialogue in which pharmaceutical companies and payers look for common ground with the ultimate goal to secure innovation at a sustainable cost and a "fair" price.

STEP 1
PHARMACEUTICAL COMPANIES AND PAYERS COME TO AN AGREEMENT ON WHAT CONSTITUTES VALUE

In our framework, value has two components:
a) Value level: what entity are we paying for?
b) Value definition: what value is guaranteed?

This concept is shown in Figure 1.

The vertical axis represents the entity the price tag is attached to. Here, we see three options:

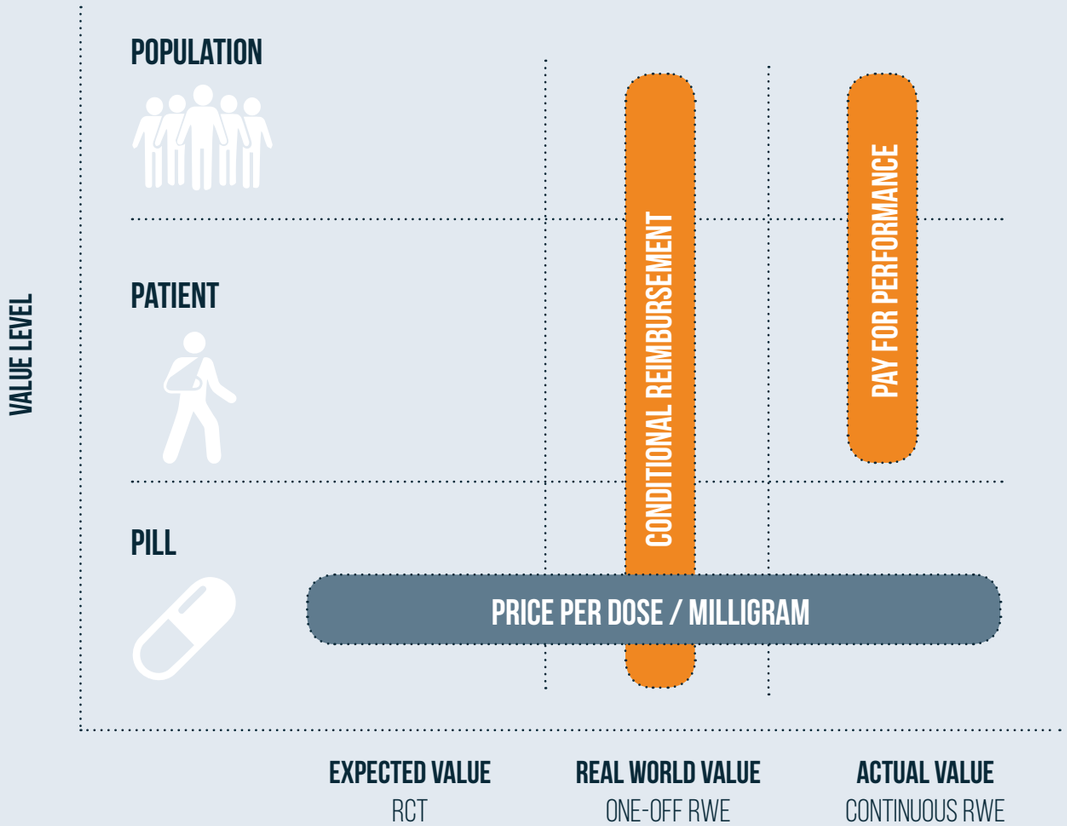
- Pill-based model: the value is determined at the level of a single medication (pill, injection, etc.), which means the volume purchased is calculated using the number of pills bought.
- Patient-based model: the value is determined at the level of the individual patient, which means the volume purchased is calculated using the number of patients treated.[3]
- Population-based model: the value is determined at the level of the population, which means the volume purchased is calculated using the size of the catchment population and expected number of patients within this population.

Box 2 provides an example of pricing beyond the level of the product as one by Microsoft Office.

3. This is in line with the opinion of Expert Panel on effective ways of investing in Health (report to the European Commission, 2018), that payment systems should evolve in the direction of paying for acquisition of a service (i.e. treatment) and not of a product (i.e. pill).

FIGURE 1:

PRICING MODEL OPTIONS



4. RCT: randomised controlled trial; RWE: real-world evidence (evidence generated in real-life, outside of the RCT setting). RWE can include pure medical outcomes, as well as patient-reported outcomes (PROs).

For all three models (pill-based, patient-based and population-based), three types of value can be guaranteed (see the horizontal axis in Figure 1):

- Expected value: expected value, based on randomised clinical trial (RCT) outcomes.
- Real-world value, determined in a sample population: value received in the real world, based on a one-off real-world evidence (RWE) study to confirm RCT outcomes.
- Actual value, determined at individual patient level: actual value received, based on continuous monitoring of RWE at individual patient level.

Box 3 describes how Philips Lighting started selling actual value instead of expected value.

Classifying pricing schemes in this framework can help stakeholders in reaching a common understanding of, and making informed and joint decisions on, what value will be delivered.

BOX 2: MICROSOFT OFFICE SELLS USER LICENSES, NOT CD-ROMS

The pill-based model remains the dominant pricing model used for innovative therapies. Yet in other sectors we see how intellectual property is priced in a different way. For example, Microsoft does not sell CD-ROMs (read: pills), but rather MS Office user licenses for individual users (read: patients) or companies (read: population). The license fee is not linked to the number of CD-ROMs used (read: the pill-based model) or the cost of producing such a CD-ROM. This makes sense, since the value does not lie in the CD-ROM itself, but rather in the intellectual property it contains.

BOX 3: PHILIPS LIGHTING SELLS LIGHT, NOT BULBS

The expected value is still used as the dominant definition of value in pricing models for innovative therapies. Yet in other sectors we see how manufacturers are moving away from selling expected value and towards selling actual value. Philips Lighting has started to sell light instead of light bulbs. Rather than paying for an expected period of lighting and bearing the risk of bulb damage and energy consumption, the client signs a 10-year contract for light. In this model, Philips is incentivised to provide durable lamps and bulbs that consume little energy.

STEP 2
PHARMACEUTICAL COMPANIES AND PAYERS COME TO AN UNDERSTANDING OF THE PRICING CRITERIA

Once parties have agreed what type of value will be paid for, the discussion should turn to “what price should be paid?” First, the scope of this dialogue needs to be set: are the pricing criteria applied to all indications or is indication-based pricing applied? [5] The next step is for the parties to agree on the pricing criteria.

As shown in Figure 2, the price can be set on the basis of four cumulative pricing criteria.

- Relative effectiveness: the first principle is that decisions on pricing and reimbursement should account for the added value that a therapy delivers for patients and society. A higher price then originates from (substantially) better outcomes versus the current standard of care.

- Patient disease burden: a higher price can also be made dependent on the degree of suffering or burden to the patient associated with the disease.

Pricing based on these two criteria is referred to as ‘Value-based pricing’: the price is based on characteristics of the therapy and the disease; cost or budget criteria are not applied.

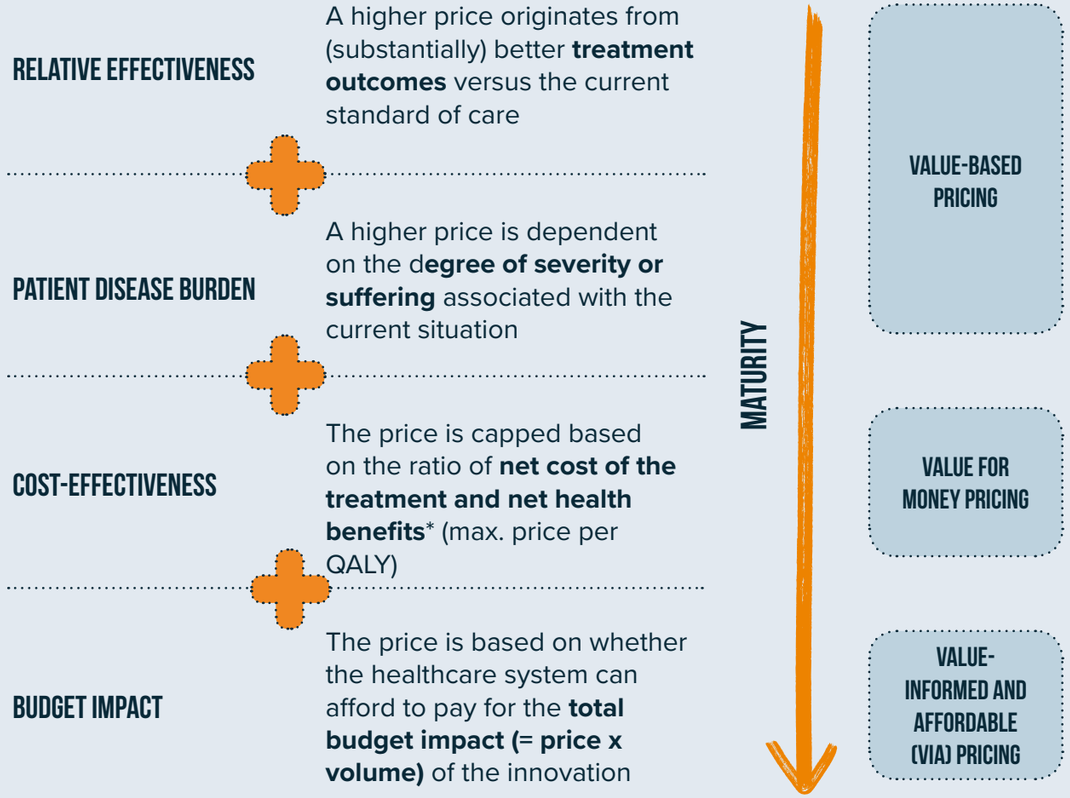
- Cost-effectiveness: in this case the ratio between the net cost of the therapy and the net health benefits is calculated as a criterion for price-setting. This is what we refer to as ‘Value for money’ pricing: a maximum amount of money a payer is willing to pay for gaining healthy life years or Quality Adjusted Life Years (QALYs) is made explicit.

- Budget impact: in this case, not only ‘value for money’ but also the opportunity costs (possible offsets elsewhere in the system) are taken into account. This

5. Indication-based pricing refers to differential pricing per sub-indication, depending on its performance against the value criteria for each specific indication.

FIGURE 2:

CRITERIA FOR PRICE-SETTING OF INNOVATIVE THERAPIES



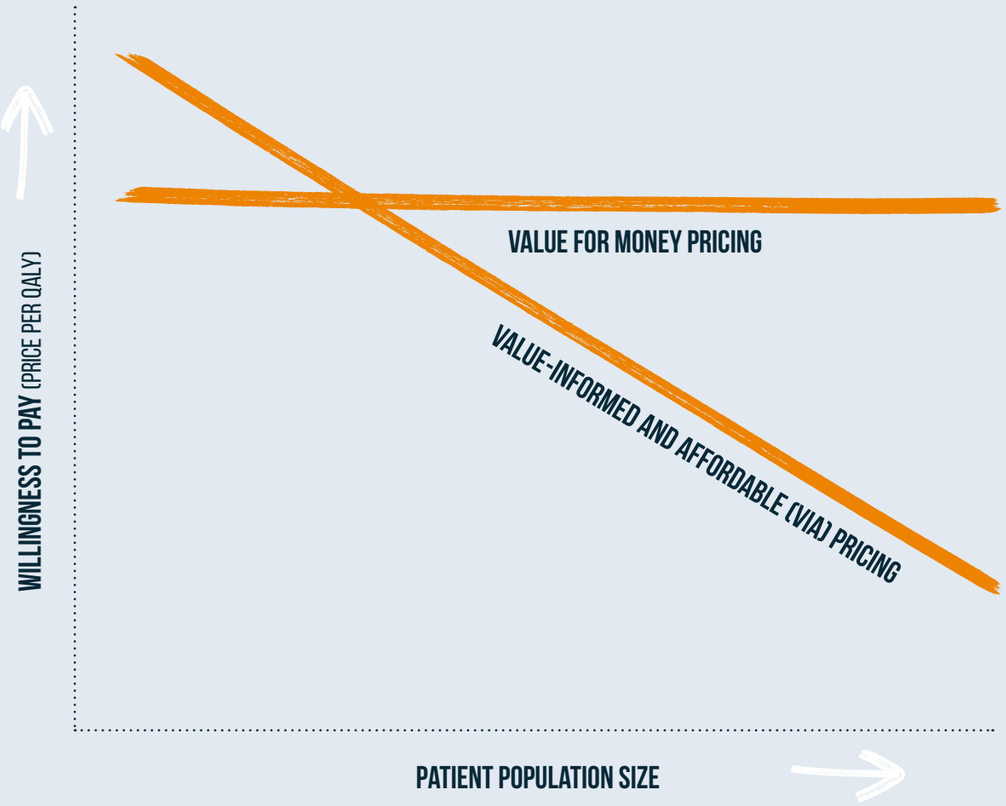
* Healthy life years or Quality Adjusted Life Years (QALYs) gained

means that budget impact analyses are required to assess the extent to which the healthcare system can afford to pay for the innovation. This 'Value-informed and affordable' (VIA) pricing implies that the smaller the number of patients, the higher the price a payer is willing to pay for each individual patient. Or that, when new indications are introduced, the price should decrease based on eligible population added. This is shown in Figure 3.

The growing supply of innovative therapies means that payers need to make difficult and tough decisions on their willingness to pay, taking into account cost-effectiveness and budget impact. Making these decisions in a transparent and consistent manner will align pharmaceutical prices with what society considers valuable.

FIGURE 3:

VALUE FOR MONEY VS. VALUE-INFORMED AND AFFORDABLE (VIA) PRICING



STEP 3
PHARMACEUTICAL COMPANIES AND PAYERS AGREE ON THE PRICE DYNAMIC OVER TIME

Thirdly, parties can jointly assess whether and how the price of the new therapy should be subject to change over time.

- More value for more money: currently, the price of a new therapy is based on the price of the latest standard of care, plus the price of the newly added value (see Figure 4). This pricing dynamic leads to ever- increasing prices of innovative therapies.

- More value for money: one could also price a new innovation at the same level of the latest standard of care (adjusted for inflation) while the price of the former standard of care decreases over time, as shown in Figure 5. In this way, more value is received over time for the same amount of money.

FIGURE 4:

PRICING BASED ON MORE VALUE FOR *MORE MONEY*

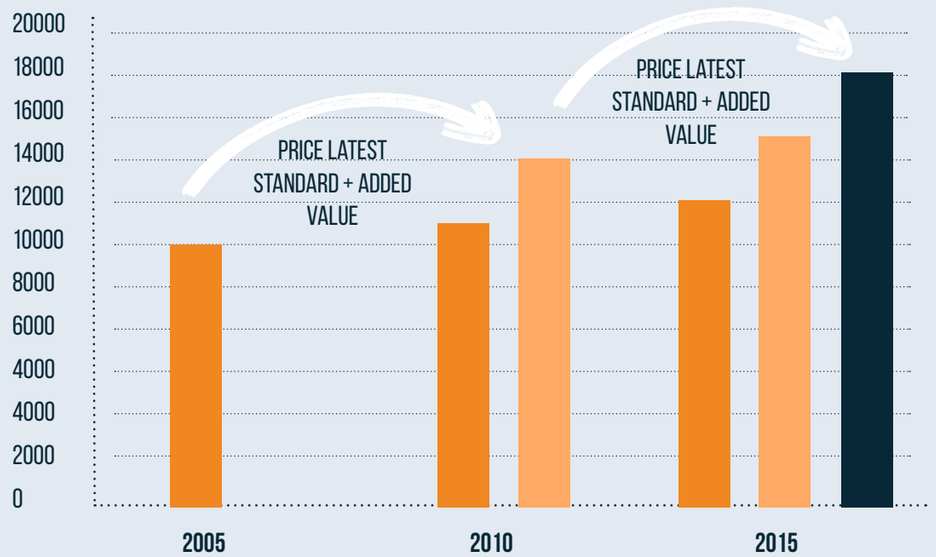
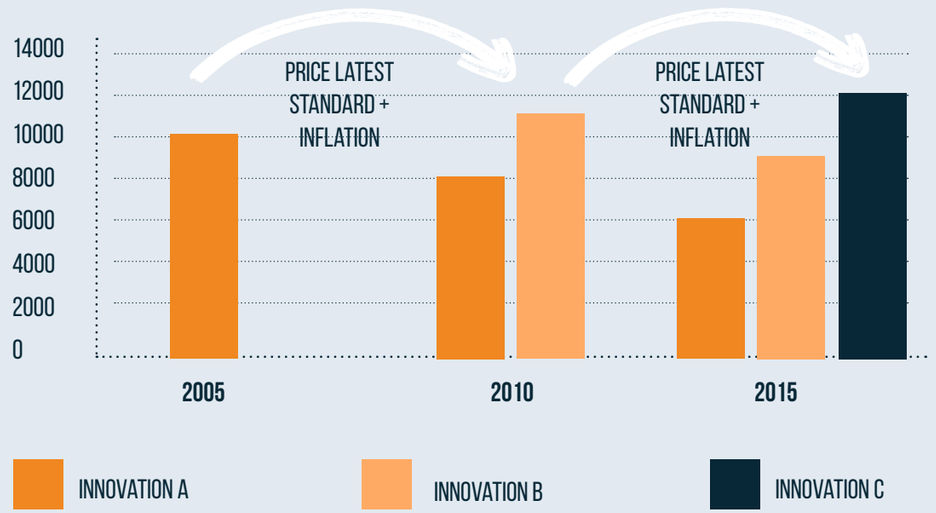


FIGURE 5:

PRICING BASED ON MORE VALUE FOR *MONEY*



When we take Apple's iPhone as an example, we see how the price of the current standard decreases as a new innovation or next generation is introduced (see Box 4).

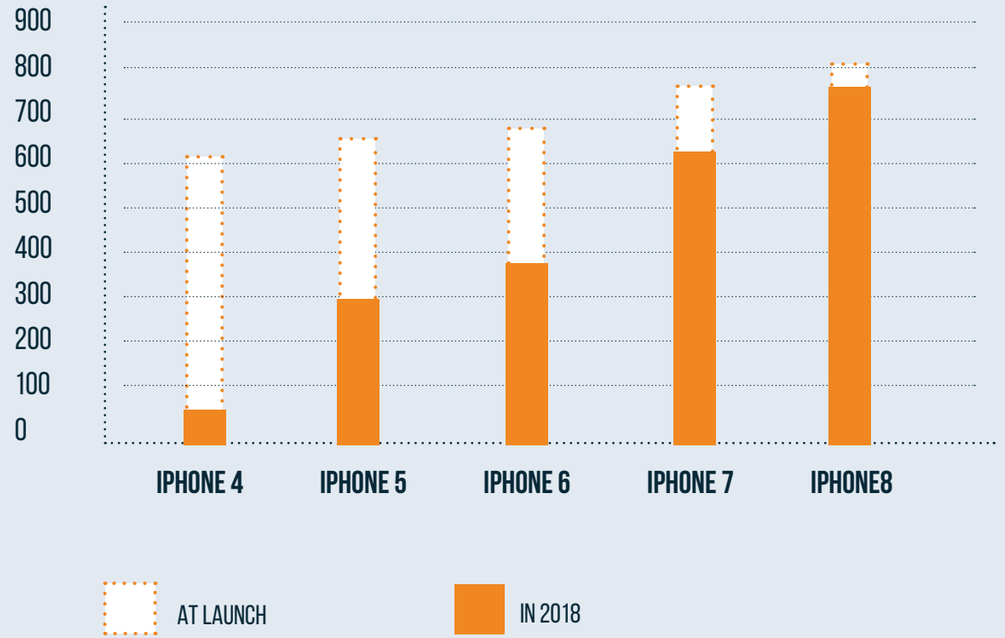
Pharmaceutical companies and payers can assess whether this model could be applied to the therapy under scrutiny as well, as a means to curb the overall budget impact of innovative therapies and to secure access to new innovations within the context of tight health budgets.

BOX 4: THE PRICE DYNAMIC OF APPLE'S IPHONE

When the iPhone 4 was introduced in 2010, it cost EUR 600. But with the subsequent launch of new iPhone models, the price of the iPhone 4 gradually decreased, down to 10% of its original price when the iPhone 8 was launched in 2017, at a price of EUR 769.

FIGURE 6:

THE PRICE DYNAMIC OF APPLE'S IPHONE



STEP 4
PHARMACEUTICAL COMPANIES AND PAYERS AGREE ON RISK SHARING AND THE PAYMENT SCHEME

Finally, the various parties need to agree on the distribution of risk and a payment scheme. Whereas pharma headquarters are the main decision-makers when it comes to the pricing model dialogue, local operating companies have a large role to play in engaging in this contractual arrangement dialogue with payers. They have three options regarding the risk-sharing mechanism:

- No risk-sharing: parties can agree to apply discounts or bonuses, without sharing risk. A discount or bonus can be applied in general; or when the therapy is used in adherence to good protocols, optimising the value of the therapy (see Box 5).

- Risk-sharing based on volume: another option is to share risks associated with the volume purchased[6], since this can be difficult to predict in advance. Total cost to payer can be reduced through a price-volume agreement or can be capped at a certain volume purchased. For the latter, an example is to install a cap for the entire population (budget cap): after this level, every additional pill will come without additional cost. Another example is to install a cap at the level of the patient (usage cap): total cost per patient is capped at a certain number of pills or treatments used (see Box 6).

- Risk-sharing based on outcomes: a third option is that parties agree to share risks related to outcome: the price to pay depends on the success of the therapy in real life (see Box 7). This requires a data infrastructure for collecting RWE (e.g. a phase IV clinical trial, patient registry or access to data in electronic medical records) and clear and agreed upon clinical end-points (or surrogate end-points/ markers).

6. Depending on the pricing model, volume purchased refers to the number of pills bought or number of patients treated. In the case of a population-based model, the volume purchased will be known in advance.

BOX 5: MERCK OFFERS A DISCOUNT BASED ON ADHERENCE TO GOOD PROTOCOLS

The U.S.-based insurance company Cigna used Merck's Januvia and Janumet in conjunction with diet and exercise to improve blood sugar control in adults with type 2 diabetes. If at the end of the year, blood sugar levels improved, the discounts Merck offered would increase.[vi]

BOX 6: NOVARTIS INSTALLS A USAGE CAP

Novartis' recommended dose for Lucentis (a therapy for wet age-related macular degeneration) was 12-24 injections per patient, but NICE specified 14 doses as its cost-effective recommendation. To maintain reimbursement, Novartis agreed to cover the cost of any injections beyond the 14th dose.[vii]

BOX 7: CONDITIONAL APPROVAL OF ASTRAZENECA'S BRILINTA

Brilinta, a blood thinner used in acute coronary disease, may reduce hospital readmission, but this outcome had to be demonstrated in real life in order for the payer (Harvard Pilgrim Health Care in the United States) to be able to make the trade-off between potentially reduced long term readmission cost and potentially increased near term drug cost.[viii]

Figure 7 summarizes the three risk sharing options and how they can be operationalized.

Once the distribution of risks is known, the payment scheme can be discussed: how are payments made and how are discounts received? A discount can be included in the payment or can be applied in the form of a rebate (on what has already been paid). In the case of pay for performance, for example, a "success fee" can be paid only for patients that respond to the therapy, or a "rebate for non-performance" can be applied. Another example is a "free initiation scheme" in which the initiation period is free of charge to ensure that patients who stop within the initiation period due to non-adherence and/or non-response are not paid for. For a breakthrough curative treatment, instalments over a longer period of time may be a useful to spread high acquisition cost over different years, to generate up-front affordability of the therapy (see Box 8).

BOX 8: SPARK AND PAYMENT THROUGH INSTALMENTS

Luxturna is a curative gene therapy for a rare form of blindness that currently costs more than $800,000 per treatment. The high up-front cost poses a problem to payers, who need to pay from a tight and fixed annual budget. Spark's contract with payers included a rebate program based on proving effectiveness (at 30 to 90 days, and again at 30 months) and an instalment that is spread over many years. [ix]

Classifying risk-sharing and payment schemes in this framework can help stakeholders in reaching a common understanding of, and making informed and joint decisions on, what risks will be shared and how payments are to be organised.

FIGURE 7:

OPTIONS FOR RISK SHARING ARRANGEMENTS

RISK- SHARING OPTION	ARRANGEMENT	EXPLANATION	APPLICABLE TO... (VALUE LEVEL)	TYPE OF RWE INVOLVED
No risk sharing ("financial-based schemes")	Discount	Flat-rate discount.	• Pill • Patient • Population	
	Partial capitation	Bonus for adherence to good protocols.	• Pill • Patient • Population	Continuous RWE
Risk sharing based on volume ("financial-based schemes")	Price-volume agreement	Variable discount based on volume: a discount is applied above a certain volume/dosage purchased.	• Pill • Patient	
	Capping	Total cost to payer is capped at a certain volume purchased, at population level (budget cap) or individual patient level (usage cap).	• Pill • Patient	
Risk sharing based on outcomes ("outcome-based schemes")	Conditional approval	Reimbursement is linked to additional evidence of clinical value, to be re-submitted by the manufacturer after a few years for re- evaluation. Companies can submit data collected from phase IV clinical trials, from patient registries (when available) or from electronic medical records.	• Pill • Patient • Population	One-off RWE
	Pay for performance	Payment only for patients who respond to the therapy, based on predetermined clinical end-points /surrogate markers.	• Pill • Patient	Continuous RWE

WHO MAKES THE FIRST MOVE?

Our discussion framework is meant to help pharmaceutical companies and payers start a new dialogue and explore where they might find common ground. It helps to jointly develop (1) pricing models; (2) pricing criteria; (3) a pricing dynamic; and (4) risk-sharing and payment arrangements that are considered ‘fair’ to all stakeholders involved. Together they can find win-win solutions that balance the needs of pharmeceutical companies, payers and society.

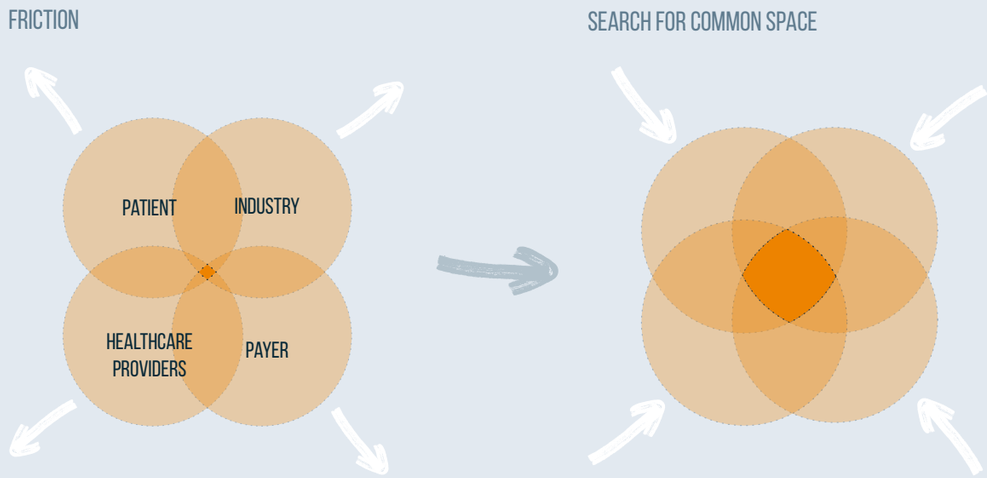
It is time that we overcome the current deadlock in the pricing debate. Stakeholders have to leave their ‘trenches’ in order to find real solutions. We should not forget that in the end we have one common goal: maintaining innovation at sustainable cost to society in order to ensure patients have access to the best possible therapies, now and in the future.

WHAT CAN VINTURA DO FOR YOU?

At Vintura, our ambition is to align stakeholder needs to maximize the common space (see figure 8). Our extensive national and international experience in strategy and organizational change in the pharmaceutical industry, combined with access to internal and external subject matter expertise, positions us as your go-to-partner for your market access and pricing challenges.

FIGURE 8:

ALIGN STAKEHOLDER NEEDS TO MAXIMIZE COMMON SPACE



We see friction in the healthcare system, pushing stakeholders away from each other.

We seek to align stakeholder needs to improve the healthcare system in a sustainable way.

Our solutions in the pricing area are structured across three capabilities:

- Pricing strategy: develop a compelling pricing strategy for your product that maximizes both payer and company value.
- Value demonstration: support business case development towards payers.
- Payer validation: obtain timely and honest feedback via our payer network.

Vintura has an extensive network of over 100 European payers and former payers, covering national and regional payers, proxy-to-payers, hospital payers and health economics experts. We can leverage this network via interviews, surveys or advisory boards to understand the most optimal pricing and reimbursement strategy for a new product; to validate payer interest in innovative pricing models; and to understand how payers and pharmaceutical companies can work together on innovative pharmaceutical pricing. With our proven approach we will deliver the first results within 4 weeks.

Let’s find the common ground, together!

FIGURE 9:

PAYER VALIDATION APPROACH

PAYER PHONE INTERVIEWS

PAYER SURVEY

PAYER ADVISORY BOARD

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SOURCE LIST

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COLOFON

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