



ADDRESSING HEALTHCARE CHALLENGES:

**Novel Pricing and Payment Models:
New solutions to improve patient access**

July 2020

Scientific progress continues to deliver new treatments that prolong survival and significantly improve the quality of life of patients. Novel treatment options introduce new challenges for healthcare systems, often requiring novel pricing and payments models.

The industry believes that when used appropriately and tailored to the situation and specific uncertainties, novel pricing and payment models can accelerate patient access, allowing payers to manage clinical uncertainty, budget impact and sustainability of the healthcare system, whilst providing sufficient incentives for innovation. Although there are examples of novel pricing and payment models being used today, the lack of appropriate data infrastructure, legal barriers and an unwillingness to adapt current systems often prevent their use.

To help address these barriers, the industry proposes a set of guiding principles regarding the use of novel pricing and payment models:

1. **Access Principle:** Novel pricing and payment models should facilitate broad and timely patient access whilst balancing the sustainability of the healthcare system and incentives for innovation.
2. **Value Principle:** A high quality, methodologically robust and mutually agreed value-based framework is the foundation for novel pricing and payment models.
3. **Collaboration Principle:** Payers and companies should work together to anticipate where novel pricing and payment models are needed and ensure they are fit for purpose.
4. **Transparency Principle:** There should be transparency regarding the existence of the novel pricing and payment agreements and the outcomes data generated (with appropriate safeguards in place), while retaining confidentiality of commercial terms.
5. **Infrastructure Principle:** Stakeholders should work together to ensure the required data infrastructure is fit for purpose and legal frameworks are in place to enable the use of the different novel pricing and payment models.

We believe that we, as the industry, have an important role to play and commit to an open dialogue and collaboration with payers and policy makers to reach a win-win solution putting patients' interest first.

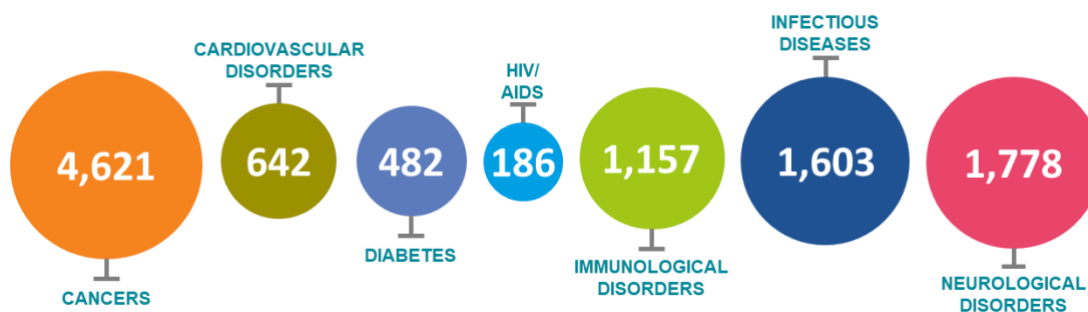
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Delivering transformative medicines to patients, the healthcare system and society

In recent years we have seen the fruits of significant scientific advances and investment in the development of new and innovative technologies. This has resulted in a healthy industry pipeline (Figure 1), evidenced by over 7,000 medicines in development across a wide variety of therapeutic areas,¹ new diagnostic techniques, genomic research and advances in data analytics—reflecting an increased focus on personalised medicine.

Figure 1: Medicines Pipeline²



Scientific progress is delivering innovations across areas of high unmet need, bringing long-term benefits to both patients and society:



Curative medicines

Curative medicines, such as gene and cell therapies or curative treatments for Hepatitis C and oncology, deliver significant benefits to patients and society. However, when applied to a large number of patients, curative medicines have posed funding challenges for healthcare systems.



Combination and multiple indication therapies

Improved understanding of disease pathology has enabled the use of **targeted therapies** across different diseases, for example advances in immuno-oncology have led to the development of tumor-agnostic therapies for several types of cancers, and **biologics** such as tumor necrosis factor inhibitors for multiple **chronic inflammatory conditions**. **Use of such medicines across indications and combinations** are increasing the quality of life and survival of patients in previously hard-to-treat conditions but bring challenges with value-based pricing and budget impact.



Disease modifying treatments

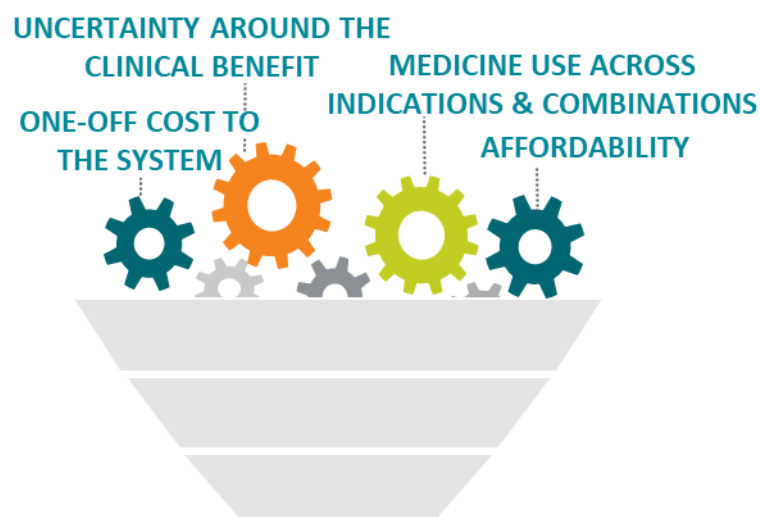
Scientific progress has also resulted in **disease modifying treatments** for **chronic diseases** with high unmet need, often prevalent in an aging population. These include treatments for Multiple Sclerosis and other neurodegenerative disorders, and continued research in Alzheimer’s disease, that could significantly improve outcomes. However, such treatments raise concerns about affordability and budget impact given treatment duration, the number of patients and potential uncertainty around real-world outcomes.

One example of recent scientific progress are gene and cell therapies. There are 34 gene therapy medicines currently in pivotal trials with several having been approved in the last two years. The expected benefits to patients and the healthcare system are significant. These could significantly increase the life expectancy of people affected by cancer or in-born genetic disorders with just a single administration. As a type of a targeted therapy, they increase the efficiency and effectiveness of treatment pathways, offsetting costs associated with chronic therapy and disease management and reducing emergency hospitalisations.³ The benefits to individual patients then translate into long-term societal benefits – people live longer, healthier and more productive lives, contributing to the economy and alleviating the impact on caregivers.⁴

New challenges and opportunities in healthcare

Novel treatments as a result of significant scientific advances—particularly the increasing personalisation of treatment strategies—offer significant benefits to patients but also pose new challenges that current pricing and reimbursement models struggle to address:

Figure 2: Observed challenges to healthcare systems due to new and incoming technologies



- * **One-off cost to the system:** In the case of one-off curative treatments, such as gene and cell therapies, payers face the challenge of a single upfront payment whilst the benefits of curing a patient occur many years into the future and extend to areas beyond savings in the healthcare system.
- * **Uncertainty around the magnitude and duration of clinical benefit:** The impact of a new treatment can be to significantly prolong patient survival and in the long term dramatically improve outcomes versus current standards of care, which may not be captured during clinical trials. Expedited access to such treatments is vital in cases where patients are facing a poor prognosis without alternatives. The impetus for rapid development and the avoidance of unnecessary delays is therefore high and has led to medicines being approved with earlier phase data based on smaller populations and sometimes only single-arm trials, especially for rare conditions. Payers sometimes face uncertainty regarding the real-world value and extent of the benefits of treatments at the time of assessment. Tracking treatment response of individual patients or sub-populations over a long period of time is an associated challenge.⁵
- * **Medicine use across indications and combinations:** Given advances in our current understanding of disease pathology and different mechanisms to target the underlying cause of a disease,^{6,7} novel therapies can have applications in a range of different patient populations, across different disease areas and in combinations. Medicines may deliver significantly different value across a range of contexts,

whereas current pricing and reimbursement processes are often rigid in assigning a single composite value to a medicine. Not all healthcare systems are able to measure the degree to which a product is used in one indication versus another, or in combination with other products, to provide a payment reflective of the number of patients treated by indication. Multiple value assessments of multi-indication and combination therapies could result in administrative burden and may delay access.

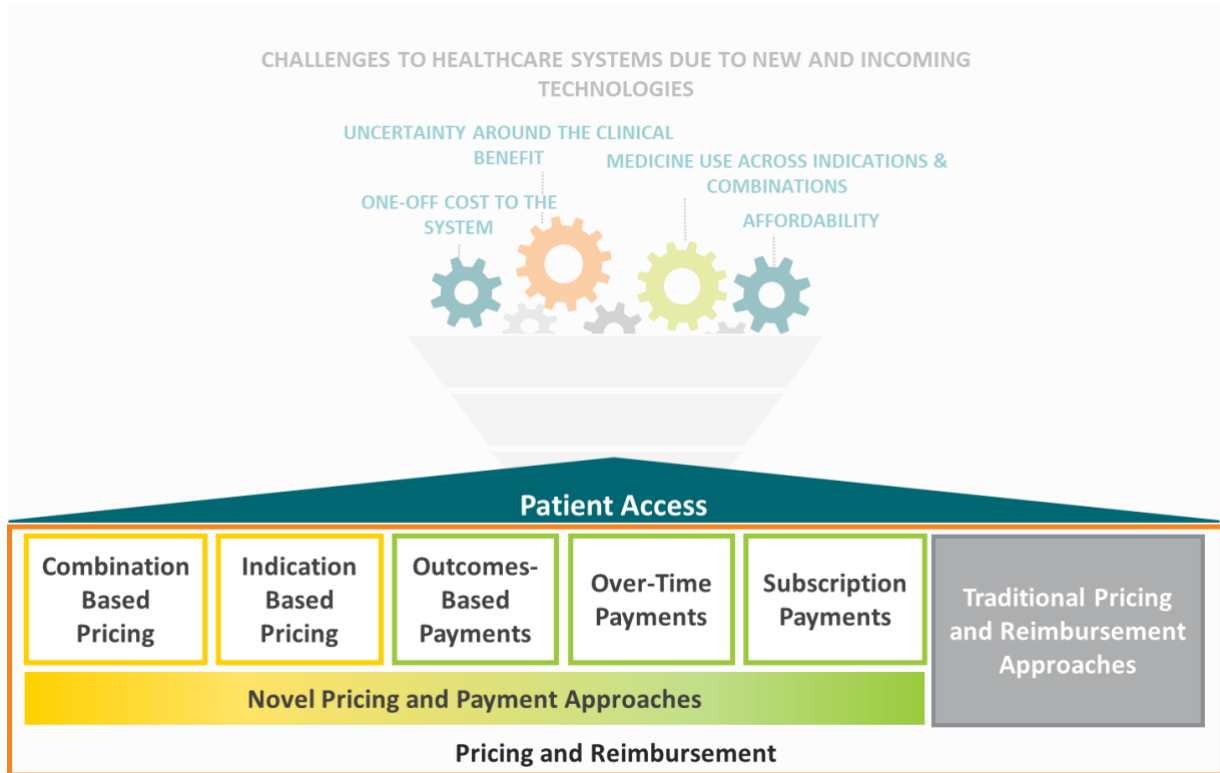
- * In addition to payers' existing **affordability and budget impact concerns**, these challenges could pose a barrier to equitable and timely access of patients to these treatments.⁸

Novel pricing and payment models are needed in specific cases, and can help address uncertainties

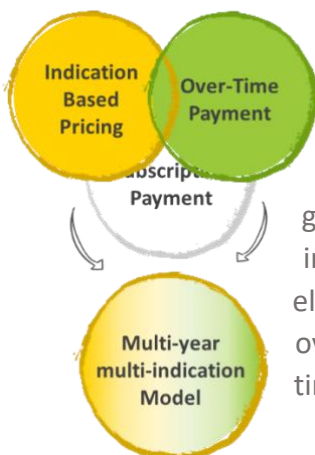
Given these new challenges it is unsurprising that traditional pricing and reimbursement models can become a barrier to patient access, and a different approach including novel pricing and payment models may be required. Novel pricing and payment models can incorporate a range of different approaches helping to address the different challenges discussed above – and could represent an alternative to existing systems based on arbitrary rebates, simple price-volume agreements and budget caps. They are dynamic and evolving, with new models developing over time. The approaches are described below and in Figure 3:

- * **Indication- and combination-based pricing:** Indication-based pricing is grounded on the notion that a medicine used for multiple indications may offer different benefits to different groups of the patients and the value of the medicine may differ by indication.⁹ Indication-based pricing is a mechanism where the price of the product reflects its observed value across indications.¹⁰ Combination-based pricing addresses the challenge that the value of products used in combination is not simply the added value of the medicines used separately. It seeks to resolve the additional complexities in assigning value and negotiating prices when different marketing authorisation holders are responsible for individual medicines used in combinations.¹¹
- * **Outcomes-based payments:** Payment for a medicine is conditioned on its real-world performance through a financial structure and is related to observable outcomes. These can be useful access tools in cases when the magnitude and durability of the clinical benefits or the medicine's real-world performance at launch may to some extent be unclear. There are a range of outcomes-based payments tailored to particular concerns. For example, coverage with evidence development allows access to the product on the condition that additional evidence is provided at a defined point in time, designed to address uncertainty at the time of evaluation.
- * **Over-time payments:** Also referred to as staggered payment, these allow for payers to make payments to manufacturers over fixed periods for each patient that receives therapy. Structuring payments this way helps mitigate the high up-front cost that would otherwise be associated with one-off therapies. When the over-time payment is linked to a particular outcome being observed, necessitating the collection of real-world outcomes data, these can also be a way for payers to address uncertainty around the clinical benefit due to the nature of the evidence available at launch.
- * **Subscription payments:** In some circumstances, these may be used to decouple payment for a treatment from the number of patients that receive the medicine. Given that the payment is delinked from the number of patients treated, such a model could help payers to anticipate the budget impact associated with treating patients in a given disease area and ensure its sustainability in the long run. There is a distinct form of lump-sum payments, where a fixed amount is paid for a given volume.

Figure 3: Different approaches incorporated into novel pricing and payment models



Note: The definition of novel pricing and payment approaches excludes simple discounts, rebates, price-volume agreements or caps to manage affordability. Pricing approaches relate the price to the value of the product to patients. Payment approaches condition payment on the value of the medicine in terms of observable outcomes, or overall de-link the payment from when the treatment is delivered.

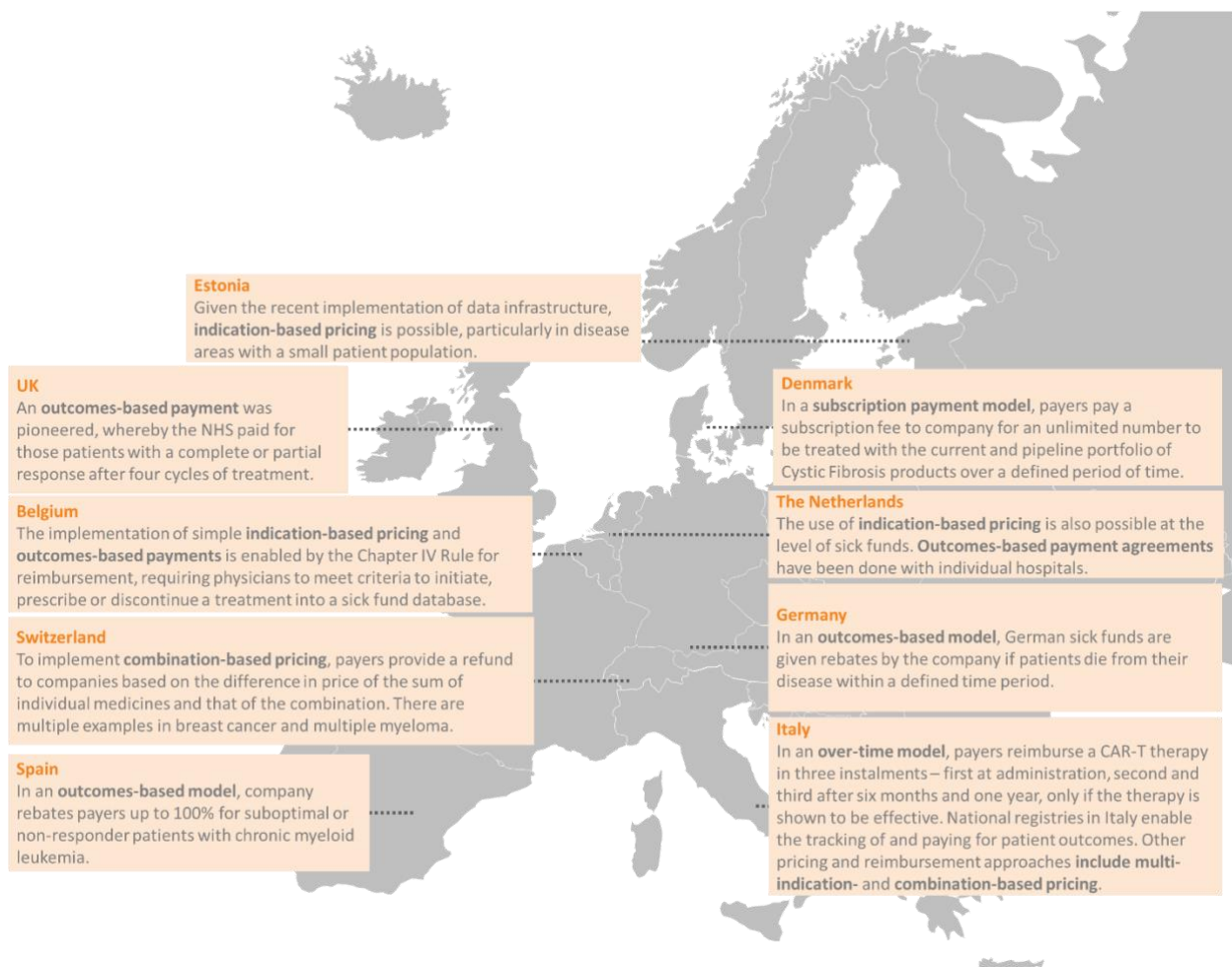


In reality, these novel pricing and payment approaches are often combined into a novel pricing and payment model, depending on the challenges related to reimbursing the treatment. For example, anticipating multiple current and potential future indications of a given product, payers and companies have in the past reached multi-indication multi-year agreements. These can be seen as combining elements of indication-based pricing and the elements associated with over-time or subscription models (an agreement for a fixed period of time, often multi-product and with rules to improve budget certainty).

We should also distinguish between the objective of the scheme and how it is designed. There have been attempts to simplify some of the more complex attributes of the models – conditioning the outcomes-based payments on medicine’s utilisation or surrogate end-points (such as cycles of therapy received) rather than patient outcomes.

Based on the experience of using these models today, there is already evidence to show how they can accelerate and broaden patient access, and contribute to improving the sustainability of healthcare systems.¹² Nevertheless, countries in Europe have varying levels of experience. Figure 4 illustrates some of the most notable examples that are in the public domain. The use of combination- and indication-based pricing alongside outcomes-based payment models requires an infrastructure to collect data regarding the medicines' utilisation or to record patients' response to the treatment in the form of outcomes. To address the challenge of paying for the value of therapies with curative potential, pricing and reimbursement approaches have incorporated over-time payment elements. For example, over-time payments have been implemented in Italy and at the level of individual sick funds in Germany. Models focusing on subscription payments are rarely used in Europe today but there is an example in Denmark. Beyond Europe, their application has been considered and some elements incorporated into agreements for Hepatitis C in some U.S. states

Figure 4: Examples of different novel pricing and payment models



Source: Based on a number of public sources.^{13,14,15,16}

The barriers and enablers to developing different types of novel pricing and payment models

Novel pricing and payment models can, in specific circumstances, ensure patient access and address potential payer challenges around sustainability, uncertainty and affordability. Thus, it is important to identify and address the barriers to their use.

Pricing and payment models that rely on the collection, processing and analysis of outcomes and utilisation data (depending on the level of adaptability of the healthcare system) will require the technical framework to manage the new types of negotiations, the development of appropriate data infrastructure and the political willingness to adapt current practice.



Legislative Barriers

The legal and regulatory frameworks across European countries have not yet fully been updated to accommodate the dynamic nature of novel models by payers and the pharmaceutical industry. The need for legislative changes varies significantly. In some markets, all novel pricing and payment models are already possible. However, in others changes are or have been required. In Belgium, for example, legislation enabled the use of different forms of managed entry agreement. Payments over time may create issues with liabilities for future payers and/or governments. In Sweden, economic regulations in healthcare prevent governments from passing on financial obligations to those in succession, which means that some forms of over-time payments would not be feasible. Lack of appropriate legislative frameworks in some countries may also present a barrier to pricing and reimbursement processes for multi-company combinations.



Lack of Data Infrastructure

Lack of the necessary data infrastructure, in the form of patient registries, electronic patient records and/or payer databases (for example, recording the volume of reimbursed medicines), is often cited as the single most significant barrier to the implementation of novel pricing and payment approaches. Data collection is also a necessary prerequisite for indication- and combination-based pricing and outcomes-based payments to be feasible, namely through tracking utilisation of medicines in different contexts and recording patient outcomes in the real world. The healthcare systems that are leading in the use of novel approaches are those with existing mechanisms for data collection such as Italy, some regions in Spain, and Estonia. An additional barrier is the lack of defined governance frameworks on data sharing, a dispute resolution mechanism, quality standards on data collection, and agreement on the process for undertaking data analysis and interpretation.



Need for System Change

Adopting new solutions always presents challenges. There needs to be a willingness to change the rules, when required, and to experiment. Companies and healthcare systems need to overcome the risk aversion due to the limited experience with these models,

learning from past successful and unsuccessful agreements. Working together could ensure that novel pricing and payment models become a valuable future option for patient access where traditional pricing and reimbursement would otherwise fail to deliver for patients. The industry has an important role in understanding the concerns of stakeholders and developing mutually acceptable solutions. Improved communication is also needed to raise awareness of and ensure the support from patient groups, physicians and the wider society of the positive role novel pricing and payment models can play, buttressing political will.

Industry principles that facilitate the use of novel pricing and payment models

If these barriers are overcome, novel pricing and payment models have the potential, in the right circumstances, to improve patient access, while helping payers address the challenges with funding the different types of novel treatments. To shape and guide discussions on future novel pricing and payment models, the industry has developed the following principles:

Principles for Novel Pricing and Payment Models

Access Principle: Novel pricing and payment models should facilitate broad and timely patient access whilst balancing the sustainability of the healthcare system and incentives for innovation.

Value Principle: A high quality, methodologically robust and mutually agreed value-based framework is the foundation for novel pricing and payment models.

Collaboration Principle: Payers and companies should work together to anticipate where novel pricing and payment models are needed and ensure they are fit for purpose.

Transparency Principle: There should be transparency regarding the existence of the novel pricing and payment agreements and the outcomes data generated (with appropriate safeguards in place), while retaining confidentiality of commercial terms.

Infrastructure Principle: Stakeholders should work together to ensure the required data infrastructure is fit for purpose and legal frameworks are in place to enable the use of the different novel pricing and payment models.

Access Principle: Novel pricing and payment models should facilitate broad and timely patient access whilst balancing the sustainability of the healthcare system and incentives for innovation.

- Patients' interest should be put first in decision making. Broad, equal and timely patient access to novel treatments across Europe should be the guiding and uniting principle for payers and the industry alike when considering novel pricing and payment models.
- Novel pricing and payment models are important tools to support broader patient access to potentially breakthrough treatments. If used appropriately, at the same time, they enable policymakers to manage the sustainability of healthcare systems and to control healthcare budgets, while providing the right level of incentives for R&D, ensuring future access to cutting-edge treatments.
- To avoid patient access delays, stakeholders should be transparent about the challenges of new treatments upfront, initiate dialogue earlier on and collaborate in designing models that address those challenges.

Access considerations for indication- and combination-based pricing

The objective of indication- and combination-based pricing should be to maximise access for every patient that might benefit from a treatment regardless of the approved indication or type of therapy used. While patient access is at the heart of these pricing approaches, indication- and combination-based pricing also provide the incentives for companies to continue to develop new medicines in the full set of indications that address unmet need, whether as mono-therapy or used in combination, based on advancing scientific knowledge. In a traditional pricing and reimbursement system, patients may not get access to some medicines or access may be delayed and manufacturers may be discouraged from investing in future indications.¹⁷ While challenges such as lack of required infrastructure to track use across indications, or the administrative burden to assessing the value of different indications, are often the focus of the debate, stakeholders should be united around the objective of providing access to all patients as quickly as possible.

Value Principle: A high quality, methodologically robust and mutually agreed value-based framework is the foundation for novel pricing and payment models.

- For all medicines, EFPIA advocates for a broad and holistic understanding of value (therapeutic value to the patient and economic value, including indirect benefits and societal value). Value assessment frameworks should be mutually agreed and should be applied consistently within a given healthcare system.¹⁸
- Novel pricing and payment models should not be used as a substitute for robust state-of-the-art HTA. Indeed, they could be a potential result of the HTA process as an option to balance risk and resolve uncertainties. Nor should they be seen as an alternative to well-designed rigorous randomised controlled trials (RCTs). They should also be applied for the relevant time period with an appropriate mechanism to re-assess the need for the agreement based on the real-world data generated. Thus, this should form part of a process for value re-assessment and price revision in line with the product's demonstrated value as some of the uncertainty is resolved. The re-evaluation process should allow for a situation where the data could show greater benefits of the treatment than originally envisaged.

Value considerations for outcomes-based payments

- A key to the feasibility and successful implementation of outcomes-based payment approaches is to keep them as simple as possible from both contractual and administrative perspectives. Some outcomes agreements can be implemented using alternative financial agreements. For example, free initiation on the medicine and continuation after a certain number of cycles if the patient responds favourably can be a simple way to address uncertainty at the start. High quality data is needed for outcomes-based payments, enabling to establish product performance and isolate it from other factors influencing outcomes in the real world. Low quality registries, inconsistent outcomes records and thus low-quality data may be a barrier to the re-evaluation of the product and its subsequent reimbursement. Whilst the measured outcomes must be carefully selected to ensure their feasibility and data accuracy, appropriate standards for data collection and incentives for physicians could help ensure quality data. Seeking independent advice from experts might help payers and companies in selecting the appropriate outcomes that reflect care patterns and patients' experience not covered in RCTs. Ensuring the buy-in of healthcare professionals and incentives are essential to feasibly collect quality data. In particular:
 - Outcomes-based payments are a useful tool for managing evidential uncertainties at launch in some circumstances, but payers and companies need to be aligned on these uncertainties, gaps in the data and outcomes measured.
 - Clear attention needs to be paid to the patient population treated, the population in the trial and the expected performance of the new treatment. Treatment guidelines have to be updated as appropriate and healthcare professionals must be aware of and apply consistently the patient eligibility criteria.

Collaboration Principle: Payers and companies should work together to anticipate where novel pricing and payment models are needed and ensure they are fit for purpose.

- Novel pricing and payment models should be used only when they are appropriate and address shortcomings of traditional pricing and reimbursement. To identify the attributes and likely challenges with incoming treatments, payers and the industry could work together to identify for which treatments novel pricing and payment models could be a viable model for patient access, at the stage of horizon scanning. Horizon scanning could provide certainty and predictability to the industry and sufficient time for payers to prepare. Earlier discussions could also ensure timely patient access.
- Novel pricing and payment models need to be fit for purpose and tailored to the specific attributes of the medicine. Payers and companies should work together to adapt conventional pricing and reimbursement as required by the nature of the therapy on a case by case basis and reach a mutually acceptable agreement.

Collaboration considerations for over-time payments

Payment over time could provide vital access to patients of curative therapies. A break from the traditional model, the value of the medicine is assessed upfront and the payment is spread over time. Depending on the country, legal barriers might limit what types of over-time payments are allowed. While the necessary legal frameworks should be in place, providing clarity on the structure and predictability for both payers and the industry, a level of mutual agreement and flexibility is also needed.

- The structure of over-time payments should be agreed on and fit for purpose, reflecting the value of the product to patients and society. If linked to the collection of patient outcomes data, payment over time could facilitate an assessment of the long-term benefits of curative therapies as these unfold over time. The framework for value assessment and price definition upfront should be based on the Value principle.
- If specific patient outcomes are monitored over time, the pattern of payments and the payment itself could be associated with a specific real-world outcome being met, as is the case of outcomes-based payment approaches. There are financial considerations in terms of payments being made by different payers over time (where multiple sick funds exist in a given market for example). This should be resolved through negotiation between payers to determine the structure of the agreements.

Transparency Principle: There should be transparency regarding the existence of the novel pricing and payment agreements and the outcomes data generated (with appropriate safeguards in place), while retaining confidentiality of commercial terms.

- The use and implementation of novel pricing and payment models could be made transparent, as could measures reflecting the benefits they deliver in terms of improved access or the overall magnitude of savings achieved by the healthcare system as a result. This could advance the debate and raise awareness of the value of novel pricing and payment models in addressing healthcare challenges amongst payers, healthcare professionals and patients.
- In order to ensure access across economically diverse healthcare systems, the financial details of the agreement and any data that could be used to derive commercial in confidence information should not be disclosed. Ensuring elements of price negotiations are commercial in confidence remains a key driver of access across healthcare systems. Increased transparency and disclosure of net prices would impact patient access to medicines negatively, especially in the case of lower-income countries.¹⁹
- Some novel pricing and payment models generate valuable real-world data on the outcomes and performance of an intervention. The exact elements of the data to be made public should be jointly agreed between payers and the company at the time of negotiations. To ensure the correct interpretation of the product's value, stakeholders should be made aware of any limitations in the quality of the real-world data compared to robust RCTs, and the context of the data collection. Thus, it is necessary to ensure that any published data are of high quality and scientific rigour, do not jeopardise regulatory approval process and the goal of novel payment and pricing models to improve patient access.

Infrastructure Principle: Stakeholders should work together to ensure the required data infrastructure is fit for purpose and legal frameworks are in place to enable the use of novel pricing and payment models.

- The appropriate infrastructure to enable data collection is a necessary requirement for some novel pricing and payment models. The different types of novel pricing and payment components require diverse interconnected and interoperable data. Combination- and indication-based pricing require tracking utilisation including volume data if the product's volume is associated with its value (e.g., time on treatment). Outcomes-based payments require tracking patient outcomes and response to the treatment in the clinical practice to determine the value of the payment over time.
- Different countries are at different stages on the route to developing robust country-level data infrastructure and the approach taken will also vary. Data collection under novel payment and pricing models should build on existing infrastructure e.g., national, regional or hospital registries, electronic or paper-based health records, patient, healthcare professionals, payer or health insurance/claims databases. Product-specific registries should be integrated in existing country-level systems to minimise administrative burden. Regardless of the approach taken, data infrastructure needs to be fit for purpose and should provide the data that allow stakeholders to reach a mutually satisfactory agreement.
- Where data infrastructure is limited, stakeholders, including payers, the industry, healthcare providers and patient organisations should work together to advance the infrastructure leveraging existing data collection platforms. The industry is open to collaborate and take some of the burden in setting these up. Adequate funding is needed for initiation but also for maintenance and improvement of infrastructure. This could be shared between the healthcare system/payers and the companies involved through appropriate payment mechanisms (e.g., pay-for-access fees).
- Key to this effort is consistency in the standards for collecting high quality, complete and longitudinal real-world data and in models to analysis and application across countries. More awareness of the use of data beyond patient management and incentives to promote comprehensive data collection are needed for high quality data as well as enough time for clinicians to record the information.²⁰
- Using data across countries in Europe is challenged by the variability in data collection across countries, different outcomes that might be measured and distinct healthcare contexts where the data is collected. European healthcare systems are already becoming more standardised and harmonised through establishing and implementing, for example, the European Electronic Health Record exchange format and the European Health Data & Evidence Network (EHDEN). However, European HTA agencies should develop appropriate standards on real-world evidence collection and use.²¹
- Once data are collected, it is important to make sure that, where appropriate, all relevant stakeholders part of the agreement, including the industry, can access the data on a suitable hardware/software platform. Patient data privacy should at the same time be maintained under the General Data Protection Regulation (GDPR).²² Appropriate

standards in line with such regulations need to define the scope for sharing and publication of the outcomes data under the agreement.

- Legal frameworks to enable the use of novel payment and pricing models and guide engagements around their negotiation are largely lacking across countries. Clear legal guidelines and policy frameworks need to be put in place that define how to engage on the types of novel pricing and payment models that are allowed and the acceptable payment and pricing structures. This can in turn provide certainty and predictability to the industry and payers in budget planning and preparation for adoption of new therapies. Appropriate legal frameworks could enable healthcare systems to use more flexible pricing approaches when needed.

Infrastructure considerations for subscription payments

Subscription payments offer payers increased budget predictability and therefore financial stability, but currently are least commonly used. Governance around product use beyond the agreed contract could be a challenge—physicians have the responsibility to adhere to treatment guidelines and the prescribed patient population. Tracking utilisation and applying reimbursement criteria might be a solution (e.g., the Belgian Chapter 4 Rule requires patients to meet reimbursement criteria for reimbursement).

- Requirements for data collection should be agreed at the start and accompanied by appropriate data collection mechanisms.
- Although not necessarily having the same data requirements as other forms of novel pricing and payment approaches, it is important to assess the value of the agreement and to be able to assess the value of new medicines that are included in the subscription model over time. Additionally, tracking patient utilisation data to ensure that prescriptions remain compliant with the terms under the agreement might also be necessary.
- Payers and manufacturers have to align on standards of data ownership and accessibility maintaining patient data confidentiality.

Conclusion: Industry commitments and enabling factors

Novel payment and pricing models can help address accelerated patient access and address healthcare challenges associated with novel treatments. For the negotiation and implementation of these to be successful, building on the above principles, the industry makes the following commitments:

1. The industry is **committed to engaging in a dialogue with countries to address potential regulatory and procedural barriers** that would be obstacles when novel pricing and payment models need to be implemented.
2. The **industry remains open to forming partnerships and commits to sharing the burden of setting up data collection platforms with payers**. Where such platforms exist and can support the use of novel pricing and payment models, the industry commits to using payers' preferred data collection platforms.
3. Recognising that successful novel pricing and payment models require collaboration from a range of stakeholders, the industry is **committed to raising awareness** of the value of novel payment and pricing models and the benefits they deliver.

There is a need for additional enabling factors that would support the use of novel payment and pricing models beyond what the industry can commit to alone.

1. **Regulatory and procedural frameworks need to be in place** to allow for the use of different novel pricing and payment approaches (such as combination-based pricing and over-time payments). This includes an openness to engage in a dialogue earlier on to ensure predictability for both parties and a willingness to adapt traditional pricing and reimbursement to facilitate the use of novel payment and pricing models when this would broaden and accelerate patient access.
2. Where there are gaps in the data collection infrastructure, **payers should be open to collaborating with the industry in building solutions**, incorporating appropriate access to the resulting information, whilst minimising the administrative burden.
3. **The value that novel pricing and payment model deliver should be assessed comprehensively**, focusing on how these can broaden and accelerate patient access, as well as their contribution to managing uncertainty and budgets.

Most importantly there needs to be a shared commitment to openly discuss the challenges and collaborate in tailoring the features of the agreement to the specific product attributes to ultimately reach a mutually agreeable win-win solution.

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² Ibid. Authors' analysis of EvaluatePharma database.

³ Ibid.

⁴ Ibid.

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- ¹² For example, between 2013 and first quarter of 2019, AIFA reported cumulative savings of just under €4 billion due to the use of financial and other novel pricing and payment approaches. (This information is based on FARMINDUSTRIA analysis.)
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