McKinsey&Company

Arnaub Chatterjee,
Casey Dougan,
BJ Tevelow, and
Amir Zamani

Innovative pharma contracts: When do value-based arrangements work?

Pharmaceuticals & Medical Products October 2017

Many are exploring alternatives to traditional 'per pill' arrangements underlying reimbursement. This holds implications for pharma manufacturers.

Pharmaceutical markets face significant uncertainty as public and legislative debates on healthcare topics continue to rage around the world. A theme common to many of these debates is a drive to manage costs through better alignment with the value of care, whether it is expressed through the reform of health policy in the United States, the implementation of health-technology assessments in Europe and Japan, or improved utilization management in many markets. Cost pressures have sparked a surge in experimentation and collaborations between manufacturers and payors or providers. As a result, innovative contracts are moving up the strategy agenda for both market-access and business leaders.

Innovative arrangements take many forms, but all represent a departure from the "per pill" arrangements that traditionally underpin pharma reimbursement. Such a departure poses questions about reimbursement, regulation, and patient management that are only now beginning to be answered. How much contracting will be done through innovative approaches remains to be seen, but this is a growing trend and looks to be here to stay. In this article, we explore the trend in innovative contracting and consider possible implications for pharma manufacturers.

What are innovative contracts?

For the purposes of this article, we define innovative contracts as any arrangement outside traditional fixed-cost-per-unit and rebating practices (meaning flat-rate discounts and variable discounts based on total volume or share). We exclude other prominent trends, such as self-imposed increase limits and transparency efforts, since they can be implemented within current structures.

Under this broad umbrella, we can distinguish three distinct categories:

- Segmentation. This heading covers indication- or population-specific arrangements that can be made unilaterally by manufacturers or in collaboration with contracting partners. Such an approach can be used where varying dose requirements make traditional per-pill or per-milliliter arrangements untenable (as with Kisqali for HR+/HER2– breast cancer).

- Contracts based on financial risk. These arrangements are intended to improve cost predictability for contracting partners—whether payors, pharmacy benefit managers, or providers—but are not linked to health outcomes. Examples include patient spending caps, case-rate arrangements, population- or volume-based spending caps, and subscription "per member, per month" arrangements. An example is Novartis's agreement with the National Health Service (NHS) in the United Kingdom to place patient spending caps on Lucentis for wet age-related macular degeneration. Although the manufacturer's recommended dose is 14 to 24 injections per patient, the National Institute for Health and Care Excellence (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.

- Contracts based on outcomes, risk, or both. These arrangements link the cost of a drug to a measure of clinical efficacy or the total cost of care of the drug in practice. They can take the form of discounts tied to clinical end points or the number of medical interventions, efficacy guarantees for nonresponders, or discounts for operational outcomes such as adherence. In recent years, these arrangements have found success in specific therapeutic areas such as cardiology. In France, GlaxoSmithKline (GSK) was required to provide evidence that its Trobalt epilepsy drug (which is no longer marketed) improved outcomes for patients not well controlled with other medication. The contract stipulated that GSK was not paid the headline cost until patients had been treated for at least 12 months, that the cost was fully reimbursed for health-insurance patients who stopped treatment within the first four months, and that for patients who stopped treatment between the fifth and 12th months, the drug was reimbursed in line with the cost of alternative treatments.

The early days

Innovative contracts are not always disclosed, but a number of these arrangements have been announced by payors and manufacturers. We conducted an analysis of more than 200 publicly disclosed innovative arrangements throughout the world since 1994, of which roughly 50 were implemented in the United States.[1] Nearly half of the contracts we looked at were in oncology and hematology, and another quarter stem from rheumatology and arthritis, cardiovascular, and endocrinology and metabolics (Exhibit 1).

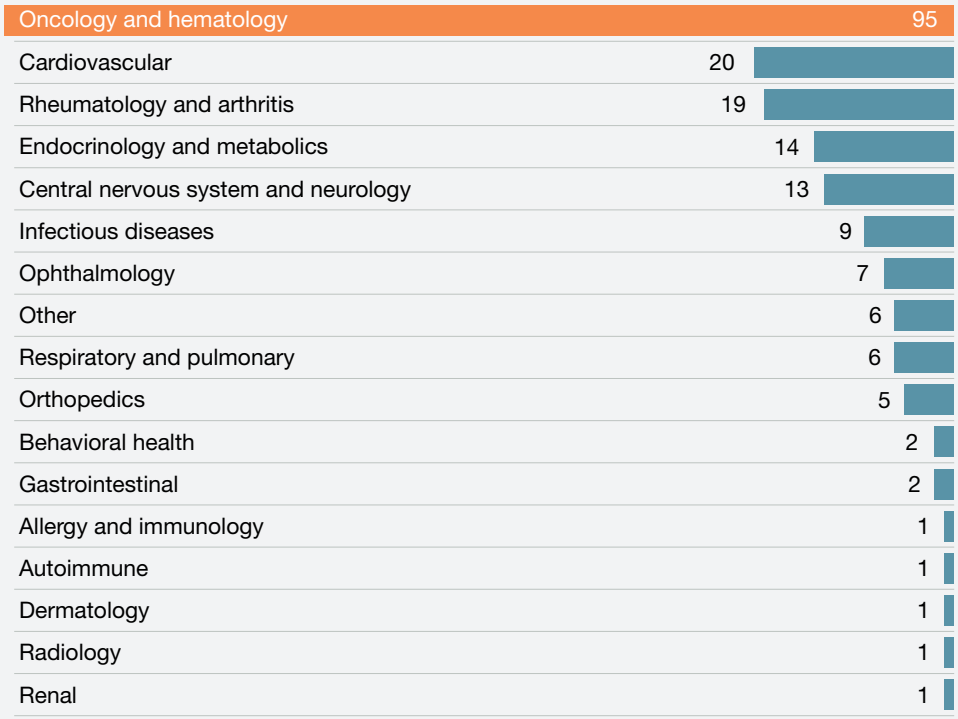
Much of this concentration is driven by national regulation. For example, Italy, which represents about 35 percent of all publicly disclosed innovative contracts (Exhibit 2), requires outcomes-based or pay-for-performance agreements for drugs in oncology, immunology, and some rare diseases.

[1] Other innovative arrangements exist on a confidential basis.

Exhibit 1

Of the publicly disclosed innovative contracts analyzed, around half were in oncology and hematology.

Global innovative contracts by therapeutic area since 1994,
number of public contracts executed



McKinsey&Company | Source: McKinsey analysis

In fact, European markets largely led the development of innovative arrangements in the 1990s, a time when the United States had no more than one innovative contract. However, US contracts began to increase in the 2000s and especially in 2014, with at least four contracts subsequently and as many as eight in 2017 to date.[2]

While innovative arrangements might be expected to offer benefits for all concerned, there is insufficient empirical evidence to prove that this is the case. With each party seeking to maximize its return, value may not accrue to all sides. Moreover, the complexity of some of these arrangements makes it difficult to predict the likely outcome at the time of contracting.

When are innovative contracts appropriate?

Our experience suggests that the presence of certain conditions may make innovative arrangements more appealing:

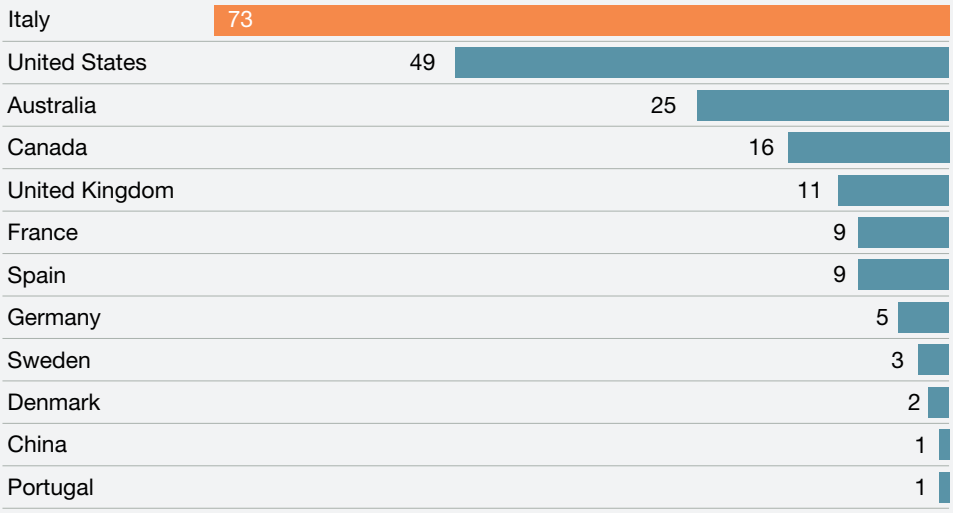
- The product is a priority for payors, with considerable value at stake. For instance, in the highly genericized osteoporosis market, the US payor Harvard Pilgrim Health Care entered into an innovative contract with the pharma manufacturer Eli Lilly to add the injectable therapy Forteo, which lists for approximately $36,000, to its formulary. Similarly, to help manage the rapid increase in hepatitis C virus treatment costs, the health insurer Cigna signed a value-based contract for Harvoni, which lists for approximately $90,000 per treatment (before discounts and rebates).

[2] In 2015, Harvoni, Sovaldi, Repatha, and Tyrx; in 2016, Entresto, Trulicity, Praluent, Gilenya, Januvia, and Janumet; in the first half of 2017, Enbrel, Forteo, Repatha (a new contract), Brilinta, Bydureon, and Kisqali.

Exhibit 2

Italy leads in the development of publicly disclosed innovative contracts, with the United States following.

Innovative contracts by country since 1994,
number of public contracts executed



McKinsey&Company | Source: McKinsey analysis

- Manufacturers need to differentiate their offerings against significant in-class competition. Repatha and Praluent were launched (by Amgen and Sanofi, respectively) within a few months of each other and compete against a host of established cholesterol-reducing therapies; both are the subject of one or more value-based agreements. Merck entered a value-based contract for its drug Januvia with the US payor Aetna in the highly competitive DPP-4 class of diabetes therapies. For Enbrel, an anti-inflammatory medicine that faces upcoming competition from biosimilars, Amgen has put in place outcomes-based contracts with the payors Medicare Australia, Ontario Ministry of Health and Long-Term Care, and Harvard Pilgrim.

- Manufacturers are challenged to guarantee value because the medical benefit is longer term and unpredictable. AstraZeneca entered an outcomes-based agreement with regional player Harvard Pilgrim for Brilinta, a branded antiplatelet medicine, to measure hospital readmission rates. The product may lower costs in the long term by reducing hospital readmissions for acute coronary disease but potentially increase near-term drug costs, creating a trade-off for payors to evaluate.

As well as considering the factors that determine whether a product is suited to an innovative arrangement, pharma companies also need to consider the conditions required to execute such a contract. These include the following:

- The ability to understand and model risk. Innovative arrangements are best suited to therapies where patient populations and clinical end points are well defined. A good example is hepatitis C therapies, which have a precisely quantified patient population (people with hepatitis C) and unambiguous clinical end points (an undetectable viral load).

Similarly, oncology therapies have clear and measurable near-term outcomes. However, innovative arrangements have yet to be adopted for pain therapies, where it is difficult to measure outcomes objectively. The same is true of antidepressants and migraine therapies, which have neither a well-quantified patient population nor unambiguous clinical end points.

- The likelihood of near-term impact. Particularly in markets where consumers change health insurers every few years, a drug that can demonstrate impact within a few months will be a better candidate for an innovative arrangement than one taking many years.

- Appropriate data-gathering, analytical, and operational capabilities. The importance of partners' capabilities is perhaps best exemplified in Spain, where care is coordinated by regional governments and risk-sharing agreements are rare. Catalonia's health ministry, CatSalut, has implemented at least seven outcomes-based contracts, each with a different manufacturer, while the other 16 regions, with some six times the patient population and five times the GDP among them, have executed only two. To implement these contracts, Catalonia developed health IT tools to monitor them and a unique personal health identifier to link data sets. In addition, its robust medical-record infrastructure allows monitoring at the population level and enables interoperability with providers.

- Commitment by both partners. Innovative contracts are more complex than traditional arrangements and require more time, resources, and patience. They are hard to execute unless both partners invest in the necessary capabilities and gain senior management buy-in.

- Viable economics for both partners. For the payor or provider, the contract could offer predictability, with or without a reduction in the total cost. For the manufacturer, the value often comes from improved access and the greater share of formulary that results from it.

Here to stay

In a rapidly changing healthcare environment where risk-based arrangements are becoming increasingly common, manufacturers should be aware of several important messages:

- Innovative contracts are here to stay. Therapeutic areas such as oncology, cardiology, rheumatology, and endocrinology and metabolics are seeing significant use of innovative contracts, and others will follow. As pharma companies gain experience tracking value in such areas, those that do not offer nontraditional arrangements will have difficulty remaining competitive.

- It's a top-management issue. Given today's uncertainties over policy and reimbursement, participation in even a few innovative arrangements can act as a strategic hedge. The question is which products, and which partners? As the industry shifts, developing a perspective on an innovative contracting strategy will be increasingly important not just for market access and global health and value executives but also for therapeutic-area leaders, heads of strategy, and C-suite executives.

- Capabilities will take longer to build. Broader engagement in innovative arrangements will require the ability to identify the most appropriate contracting opportunities, build deeper

relationships with partners, execute strong contracts, and manage ongoing risk. Payors and providers have blazed the trail to some extent through experiments with accountable care organizations,[3] "episodes of care" payments,[4] healthcare exchanges,[5] and other innovations that have exposed long-term capability needs. Building and implementing capabilities for risk- and value-based contracts, even on a small scale, may create significant long-term value.

- Traditional approaches will need to continue to be sharpened in parallel. Traditional arrangements are expected to continue to dominate contracting for the foreseeable future. As the frequency of negotiations and the value at stake increase, building the next generation of analytical capabilities, processes, and governance will be essential in positioning a brand for success.

Innovative arrangements are unlikely to replace traditional contracts in the foreseeable future, but we believe they are complementary and will become increasingly important. Pharma manufacturers should be aware of the possibilities and ready to adopt such arrangements if the conditions are right. □

Arnaub Chatterjee is a senior expert in McKinsey's North American Knowledge Center, **Casey Dougan** is a consultant in the Silicon Valley office, **BJ Tevelow** is a senior partner in the New Jersey office, and **Amir Zamani** is an associate partner in the Boston office.

The authors wish to thank Matt Cuddihy, David Quigley, Josh Sternberg, and Matthew Van Wingerden for their contributions to this article.

[3] Accountable care organizations (ACOs) are groups of doctors, hospitals, and other healthcare providers that organize to give coordinated high-quality care to patients and attempt to eliminate redundancy, remove duplication in costs, and improve continuity of care.

[4] "Episodes of care" payments are lump-sum payments made to reimburse providers or hospitals for the full range of care provided to a patient for a specific medical condition during a certain period of time, such as a hospital stay, a procedure, or physician care.

[5] Healthcare exchanges are state-based organizations through which individuals can choose a health-insurance plan from a range of government-regulated and standardized plans offered by participating insurers.