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Innovative pharmaceutical pricing agreements in five European markets: A survey of stakeholder attitudes and experience

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ABSTRACT

Background: Innovative pricing agreements for medicines have been used in European markets for more than 20 years, and offer an opportunity for payers and pharmaceutical companies to align on value, optimise speed to patients, and share risk. Developing successful agreements requires alignment between key stakeholders, yet there is a lack of summative data on how current innovative agreements are used in the real-world (e.g. the level of realised access to medicines, and rebates and discounts, which are often non-transparent).
Methods: This research used a web-based survey of payer stakeholders to determine what kinds of innovative agreements are currently used, anticipated future usage, attitudes, and drivers of adoption. Participants included national and regional payers (or former payers) and hospital-level decision makers.
Results: Sixty-six payers completed the survey. Respondents expected that the use of innovative pricing agreements will remain the same or increase in the future. Overall, they felt there is a positive attitude towards new schemes, and that innovative agreements are likely to be used when they reduce total costs or reduce uncertainty.
Conclusions: Given payer expectations, pharmaceutical companies should continue to take a role in ensuring that they have sufficient capacity to support payers in the design and implementation of innovative pricing agreements.

1. Introduction

Global medicines expenditure is forecast to reach USD $1.4 trillion annually by 2020 [1], an increase of approximately 30% from 2015 levels. Given this upward pressure on healthcare budgets, balancing total spend on pharmaceuticals with the imperative to provide timely access to new medicines will be a critical priority for policy-makers. In the major European markets (France, Italy, Germany, Spain and the UK), payers, including both statutory organisations with delegated authority and compulsory/statutory health insurers, are expected to be at the forefront of finding solutions for optimising expenditure on medicines. They will need to continue using innovative approaches toward medicine pricing and reimbursement, and keep ensuring that newly launched medicines meet a number of criteria (e.g. including clinical outcomes vs. the comparator, that an unmet need is met, and that they have an acceptable budget impact) [2]. The actions of pharmaceutical companies, both in developing new medicines, and potentially in pricing those medicines, should take these needs into account.

Uncertainty about the future effectiveness and value that a new medicine offers outside the clinical trial setting, and general challenges with funding new medicines, are inherent to new medicine launches. This uncertainty means that price setting at launch can be challenging. This has led to the development of innovative agreements that go beyond an up-front price-setting negotiation or mechanism. Development of new so-called 'adaptive pathways' [3] to accelerate marketing authorisation of new medicines for patients may also be a factor in promoting new payment models as a way for payers to manage the initial uncertainty resulting from the limited amount of data available at launch.

Innovative agreements are often also known as 'managed entry agreements [4,5] (these terms can be used interchangeably; for

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the purposes of our research, we have used the term "innovative agreements"). There are two main classes of innovative agreements [6–8]: those with a purely financial emphasis (such as caps or annualised rebates on a per-manufacturer basis, list-price discounts or price-volume agreements) and those that place more emphasis on clinical performance (such as the collection of evidence through real-world studies or per-patient outcomes). National price volume agreements are routinely negotiated for new medicine launches in France [9]. In the UK, one example of a performance-based agreement is bortezomib, which is rebated for patients with multiple myeloma who do not meet specified response criteria [10]. Another treatment for multiple myeloma, pomalidomide, has a similar performance-based agreement in France [9,11]. However, despite the uptake of innovative agreements in European markets, there are critiques of the extent to which they are 'quick-fix' solutions [4], or can introduce perverse incentives into market access systems [12].

Although various types of innovative agreements have been in use since at least 1993 [13], limited summative data are available that enable analysis of trends in their adoption and success. A number of papers have sought to systematically review contemporaneous and historic pricing agreements in order to document examples of use by health-care payers and manufacturers [6,7,13,14–18]. However, the use of different definitions and taxonomies of innovative agreements makes systematic analysis and comparison across reviews difficult. This in turn creates difficulties in identifying related practices, particularly as details of existing agreements and pricing schemes are often not formally published (either by manufacturers or payer organisations).

Continued and expanding use of these schemes requires a greater understanding of payer perceptions, experience, and orientation towards their current and future use. This study was designed to gain this understanding by undertaking a survey of payers from the major EU markets, and then using the information to derive policy implications for future innovative pricing agreement proposals. There are important issues to consider with innovative agreements such as delisting of products that do not deliver on value goals or adaptive pathways and the surrounding safety and ethics questions. However, these are outside of the current research objective.

2. Materials and methods

2.1. Participants

Stakeholders (defined as pharmaceutical decision makers) from the five largest European economies (France, Germany, Italy, Spain, and the UK) took part in an online survey. These stakeholders fell into two broad categories: hospital pharmacists with responsibility for procurement decision making (including formulary inclusion and purchasing) and current or former members of regional or national healthcare payer or budget-setting organisations (including health technology assessment agencies). Recruitment across these two categories allowed opinions at both the local and the more policy-driven regional/national levels to be captured. Stakeholders were identified from a proprietary contact database, based on current or former (in countries where current payers are restricted from taking part in market research) employment with national/regional payer bodies and hospitals, and were invited to take part via email.

2.2. Survey design

The survey was web-based with closed, multiple choice questions. Stakeholders were asked about their general awareness of and direct personal experience with innovative pricing agreements, how these should be used within health economies, and who should be responsible for their initiation and design. They were also asked about their general attitudes to innovative pricing agreements and how usage of such agreements might change in the future. A list of questions included in the survey is provided in Appendix A in Supplementary materials. The survey allowed for both positive and negative responses although via a closed questioning technique.

For the purposes of this research, innovative pricing agreements included 'coverage with evidence development' (conditional market access granted on the basis of an agreed study or real-world data collection), 'financial-based risk sharing' (risk of excessive cost/budget impact is shared between the manufacturer and payer through agreed limits per patient or per treatment episode) and 'performance-based risk sharing' (payment is dependent on the medicine achieving an agreed clinical outcome, normally at the individual patient level). Simple rebates, price/volume agreements and discounts were classified as 'traditional' financial-based agreements.

Stakeholders completed the survey anonymously, although they were asked to disclose their role and country. The survey was carried out in August 2016.

The survey was programmed in Qualtrics®. Data were managed and analysed using Microsoft Excel; analysis was limited to descriptive statistics owing to the small sample size.

3. Results

3.1. Stakeholder demographics

In total, 66 stakeholders were included in the final analysis; 52% (N = 34) were hospital pharmacists and 48% (N = 32) were members of budget-setting or health-care payer organisations. Sixteen stakeholders were from the UK, 16 were from France, 12 were from Spain, 11 were from Germany and 11 were from Italy. Only 2 stakeholders had less than 5 years of experience in their respective stakeholder role; 45 (68%) had between 5 and 15 years of experience, and the remainder more than 15 years. A small number of stakeholders (<5) were excluded from the final analysis because they did not fully complete the survey.

3.2. Experience and knowledge of innovative agreements

When considering general awareness and in-market experience of agreements in use, stakeholders reported that they were most aware of the 'traditional' financial-based agreements. This was also the type of agreement that most stakeholders had personal experience with: overall, 77% said they had experience with this type of agreement (Fig. 1). Less than half of respondents overall reported experience with either financial risk sharing or coverage with evidence development. To validate reported experience, participants were also asked to estimate the current usage of different schemes in their country; results are included in Appendix B in Supplementary materials. The disease areas most frequently associated with any type of agreement (including discounting) were oncology (38% of disease/agreement combinations selected by participants in total), autoimmune therapies (25%), central nervous system and cardiovascular disease (both 13%).

Differences were seen in whether respondents thought innovative agreements should be made at the national or regional level: most respondents in Italy (67%), France (65%) and the UK (72%) preferred them to be made at a national level, whereas around half of respondents in Spain (50%) and Germany (59%) preferred them to be made at a regional level.

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