A Work Project, presented as part of the requirements for the Award of a Master Degree in Management from the NOVA – School of Business and Economics.

MARKET ACCESS CASE STUDY

Analysis of a Negotiation Between a Pharmaceutical Company and a National Health Authority

TOMÁS OLAZABAL CABRAL TORRES FEVEREIRO | 3578

Advisor: Professor Luís Almeida Costa

3rd January 2018

Abstract

Market Access Case Study: Analysis of a Negotiation Between a Pharmaceutical Company and a National Health Authority

This work project develops a case study distilled from the assessment of the current environment in the pharmaceutical industry, of its trends, drivers and geographies. A pharmaceutical company and a national health authority conduct price and reimbursement negotiations upon market access. The case focuses on the possibility of value creation through the development of package deals and contingent contract clauses in a situation where, if only a single-issue and value claiming agenda is pursued, the zone of potential agreement is nonexistent. The case also reflects upon the management of the negotiation process, and how to manage different expectations.

Keywords: Pharmaceutical Regulation; Market Access Negotiations; Value Creation.

Table of Contents

Acknowledgement

Firstly, I would like to thank Dra. Vanessa Jacinto, whose insights and expertise substantially improved my thesis and made the process of writing it a much more enjoyable and smooth undertaking. Secondly, I must recognize and thank Professor Luís Almeida Costa for all of his effort, for always making sure to be made available to help and contribute in a meaningful way. It was truly a pleasure to be able to have had him as my tutor for this work project. And lastly, I want to thank all the support from my parents, my aunt Margarida Olazabal Cabral and my grandparents, without whom I wouldn't have joined the Nova School of Business and Economics.

Part A: Case Study

Introduction

In this work project, we present a case study of a typical market access negotiation between a health authority and a pharmaceutical company in the process of launching a new drug. In particular, we consider a negotiation between Infarmed and Boehringer Ingelheim Portugal.

Infarmed (*Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.*) is the responsible regulatory authority or national HTA body in Portugal (Ministério da Saúde 2011, 13-24). Infarmed is accountable for the authorization, regulation, distribution and surveillance of pharmaceuticals and medical devices (The Economist Intelligence Unit 2015, 4-5).

Boehringer Ingelheim Portugal is the Portuguese affiliate of the multinational pharmaceutical company named Boehringer Ingelheim. The Boehringer Ingelheim group is one of the world's 20 leading pharmaceutical companies. It is 130 years old, and focuses on progress and value creation through partnerships (open innovation). The research-driven company offers products for both people and animals, operating globally with 143 affiliates and more than 45,690 employees (Boehringer Ingelheim 2017).

The case study aims to provide a real-life negotiation simulation to be used in negotiation analysis courses, both in master programs and in executive education workshops. It mimics the current environment in the pharmaceutical industry in Portugal, some of its major trends and drivers, and some of the usual complications in the market access process.

We begin by introducing the case, presenting the pharmaceutical industry and the process of launching a new drug. We also discuss their particular context in Europe and Portugal. Following, we develop the specific situation, presenting the sets of confidential information and instructions for negotiators. Lastly, after providing a case synopsis, case objectives, and courses where it may be used, we propose some questions for class discussion, supported by relevant literature.

The worldwide market for pharmaceuticals is huge. It is projected to grow to 1.3 trillion dollars by 2020. A "rapidly aging world population [associated with the rise in chronic deceases], increased urbanization and higher disposable incomes, greater government expenditure on healthcare and growing demand for more effective treatments" are some of the global demographic and economic drivers of pharmaceutic al consumption (Finn 2016, 9).

Bringing a new drug to market is a complicated affair. It may require more than a decade of R&D and an investment of more than 1 B$ (Boehringer Ingelheim 2017). Additionally, there is the need to amortize the cost of all other drugs that failed for some reason somewhere along the process. Around half of the new medicines miscarry in the late stages of clinical trials, when considerable amounts of money have already been put into their development. As little as two out of ten medicines generate returns that exceed average R&D costs. A high-stakes endeavor were companies need to ensure their revenues will be sufficient to sustain R&D investment levels, and ultimately be profitable. In short, "research-based pharmaceutical companies operate under a challenging, high-stakes business model in which the failure rate is high" (Finn 2016, 7).

Developing the medicine itself comprises three major stages: research (target identification and validation; assay development; lead identification; lead optimization; pre-development), development (preclinical development; clinical research Phases I to III), and registration (regulatory approval; Phase IV – life cycle management) (Boehringer Ingelheim 2017).

Towards the end of the development process of a new drug, namely after receiving regulatory approval, pharmaceutical companies shift their efforts towards market access. Market access approval must be obtained from health authorities. To this end, companies and health authorities may negotiate a number of variables. Variables such as the price at which the new drug will be sold in the market, and the funds to be provided by the respective national health system.

A virtuous perspective of market access is to consider it as the "process that tries to ensure that all appropriate patients who would benefit […] get rapid and maintained access to the brand, at the right price" (Wight 2012). From the perspective of a pharmaceutical company that is trying to launch a new drug, market access is "about packaging data in the right way, for the right customer at the right time, by understanding the needs of all stakeholders involved in the adoption, positioning and funding" (Dawson and Rosen 2017). Successful planning of market access is fundamental throughout the life cycle of the product.

With the surge of hi-tech drugs and enormous pressure on governments and/or healthcare systems to cut budgets, market access became increasingly important over the last decade. "Pharma and biotech companies now have to work very hard, gathering lots of data around the health economic impact and cost-effectiveness of their products and they need to present these reams of data" to health authorities in the most convincing possible way (CarrotPharma 2016).

Every new drug has to be registered by health authorities (van Boxtel, Santoso and Edwards 2008). Data from all clinical trials are collected and compiled into a document called Registration Dossier (efficacy and safety data to support the final intended use of the drug). This document is customized for each country, to meet the requirements of health authorities. An important concern of regulatory authorities is the safety of new drugs. To meet such concern, authorities monitor each new drug (European Medicines Agency 2016). Post-authorization safety updates, annual reports, and any additional information required by the health authorities must be provided at defined intervals (European Medicines Agency 2017).

A decisive trend in the pharmaceutical industry is the increase in data requirements for pharmaceutical companies to obtain reimbursement approval from health authorities. Drug reimbursement denotes "a situation where either a drug company is paid by a third party for all or part of a prescription, or where a third party repays the consumer a portion or all of the

prescription's price" (Black 2017). A decision on reimbursement is based on the incremental clinical benefit of the new drug compared with standard therapy. Health authorities will make a trade-off between the extra clinical benefit (therapeutic value) and the premium price of the new drug versus the standard therapy. Traditional registration data for the reimbursement of pharmaceutics included efficacy, safety, and quality parameters. The additional and mounting demand for effectiveness, quality of life, cost-effectiveness, and budgetary impact data already resulted in formal dossier requirements in most countries. "The growing burden on manufacturers to submit extra data for their products in the pricing and reimbursement process […] may have considerable consequences for the potential revenues of a new drug. […] The additional hurdles for market access for pharmaceuticals: 1) reduce the probability of reimbursement; 2) reduce the potential market size […]; 3) delay the period between registration and reimbursement [reducing the time period during which the company is able to commercialize the drug with the protection of a patent] […]; and 4) increase the costs for research and development (e.g. the costs of outcomes research after launch) and the costs of market access (e.g. reimbursement dossiers)" (Kogels 2009). The end result is that the financial risk for pharmaceutical companies to invest in innovation has increased substantially. The current environment for innovation presents formidable economic, regulatory, and political challenges for the research-based pharmaceutical industry (Kaitin 2010). As Finn puts it: "traditional business models are under huge pressure, and pharmaceutical companies will have to work much harder to earn profits going further" (Finn 2016, 9).

Negotiating funding terms with health authorities entails lengthy and repeated discussions. To deal with the level of complexity involved it is common to start discussions early. Some pharmaceutical companies even have the flexibility to involve health authorities in the process as early as Phase I in the development process (Stojaspal 2012).

European Context

Developed markets have high per capita spending rates on healthcare, strong IP protections and streamlined regulatory processes. A rapidly aging population, associated with a rise in chronic deceases, is a crucial driver of pharmaceutical consumption in these markets. Nonetheless, growth rates in these developed economies are expected to remain low. This is due to "stagnating national economies, tighter regulations, patent expiries and pricing pressure. In an era of global fiscal austerity, the [pharmaceutical] industry expects […] governments, particularly in Europe, to continue to put pressure on drug prices" (Finn 2016, 9).

The "environment for the pricing and reimbursement of pharmaceuticals has become increasingly challenging. Regulation in these areas has tightened and across Europe a fourth hurdle – cost-effectiveness – has supplemented the established notions of safety, efficacy and manufacturing quality as a further requirement to secure market access" (Dawson and Rosen 2017). This trend is expected to continue in the following years (European Commission 2017). The mandatory submission of extra data on cost-effectiveness, impact on quality of life and budgets, resulted in additional formal dossier requirements that companies have to comply with in most European countries: the submission of a reimbursement dossier. This document conveys and provides evidence for key scientific and commercial messages (Voisin Consulting Life Sciences 2017). The submission of a reimbursement dossier is required for any registered medicinal product to be considered for reimbursement (World Health Organization 2015). Compiling the dossier requires significant investments (Kogels 2009). The dossier is submitted to the European central authority, the European Medicines agency (EMA), or national authorities for a health technology assessment (HTA) (World Health Organization 2017). Health authorities are also increasingly demanding the validation of the claims in the reimbursement dossier by forthcoming studies after launch (Kogels 2009).

Yet another development in European price and reimbursement negotiations has been the emergence of risk-sharing agreements. “In return for a pharmaceutical company’s guarantee of efficacy, a payer [in this case, a health authority] will add a new product to its formulary that it would not have added otherwise. The concept is similar to money-back guarantee for consumer products; they provide a perception of quality and confidence. […] For new drugs, risk sharing can make a lot of sense, as the manufacturer has better insights in the strength behind its claims with respect to yet unproven health benefits” (Schoonveld and Kloss, Unpacking Risk Sharing and Alternative Pricing Schemes 2010, 1).

There are, however, a number of concerns with existing schemes (Adamski, et al. 2010). The contingency clauses may provide the conditions necessary to an agreement, or even enable the negotiation of a higher price for the drugs, but they usually entail a price discount. The main concern is that such price concessions may have a domino effect across markets. When a health authority acquires a price discount through a risk-sharing agreement somewhere, it could set a precedent. If so, health authorities in other markets may demand the same net price (Schoonveld and Kloss, Market access: Risk sharing and alternative pricing schemes 2010). Some of these deals are even seen, sometimes, as disguised price cuts or opportunistic competitive moves (Rose 2010). Critics of these types of deals usually call them *alternative pricing schemes*. They refrain from the “risk-sharing” definition, since pharmaceutical companies usually bear most of the risk (Schoonveld and Kloss, Unpacking Risk Sharing and Alternative Pricing Schemes 2010, 1-2).

Negotiations between pharmaceutical companies and health authorities tend to be drawn-out, and there is no short supply of past complications. For example, Boehringer Ingelheim decided to delay the launch of their anti-diabetic drug *Trajenta*, in Europe, until they resolved a dispute with the German Institute for Quality and Efficiency in Health Care over the choice of a comparator drug (Stojaspal 2012).

National Context

Financial constraints and the increase in medicine consumption have exerted a tremendous amount of pressure on Infarmed to comply with cost reduction policies (Infarmed 2015, 3-7). This resulted in an increasing demand for cost-effectiveness and budgetary impact data, which eventually gave birth to formal dossier requirements (alike most other European countries).

Boehringer Ingelheim Portugal is the pharmaceutical company that receives the fourth highest level of financing from the Portuguese national health system (*Sistema Nacional de Saúde, SNS*) (Infarmed 2015, 17). Boehringer Ingelheim Portugal negotiates with Infarmed independently from the company's corporate headquarters, which are based in Germany. However, it must comply with the policies and specific directives issued by the headquarters. A typical directive is the *floor price*: This is the lowest acceptable value to be negotiated with health authorities for a new drug. It is derived from the company's overall financial viability.

The maximum price to be negotiated for a drug is defined according to legislation, based on an international referral system: its given by the average price of analogous drugs in reference countries. Portugal has three reference countries: Spain, France, and Italy (Ministério da Saúde 2016). The reimbursement rates are not negotiable. They are predefined on a legal basis and dependent on its pharmacotherapeutic group as follows: 90% for group A; 69% for group B; 37% for group C; 15% for group D (Ministério da Saúde 2015, 2).

Infarmed does not strictly follow a timetable in their analysis and decisions. In 2014, the average time from regulatory approval to first sales was 13.5 months (Colasante 2015, 28, 33).

There are typically information asymmetries between pharmaceutical companies and Infarmed. Pharmaceutical companies tend to have greater access to drug development information, and more ability to process it as well. They have more resources to do so, i.e., more labor and higher budgets for such activities.

Specific Situation

In this section, we present the confidential information of Infarmed and Boehringer Ingelheim Portugal, relative to the launch of a new drug. The negotiators' sets of confidential information and instructions are presented in the following chapters: *Confidential Information of Infarmed*, and *Confidential Information of Boehringer Ingelheim Portugal*.

Negotiators will argue the terms of agreement amongst them, simulating the actual market entry negotiation dynamics between the pharmaceutical company and the national health authority. They will try to reach an agreement on the public price (PP) of the drug, the maximum value of pharmaceutical expenditure borne by the national health system, and other possible conditions, such as contingency clauses.

An answer sheet will ask for four things: if an agreement was reached; drug price (PP); pharmaceutical expenditure to be borne by the national health system (duly justified); other negotiated terms (e.g., post-authorization updates – collection and analysis of short-term results).

Confidential Information of Infarmed

Boehringer Ingelheim is one of the world's leading pharmaceutical companies. It has just developed *Arritmolus*, a promising new drug for outpatient care. This drug suppresses cardiac arrhythmia, a chronic cardiovascular disease, and prevents its symptoms and complications. Developing a new drug is a complex endeavor, requiring significant investments. It takes a decade from discovery to the approved medication, sometimes entailing investments of more than 1 B€. The new drug has already received regulatory approval in Europe from EMA (European Medicines Agency), following an assessment of its quality, safety and efficacy. The company is now looking to obtain market access, i.e., being able to start selling the medicine. This will be accomplished by first negotiating price and reimbursement terms with the health regulatory bodies of the different countries. Infarmed is the Portuguese health authority. It is accountable for the authorization, regulation, distribution and surveillance of pharmaceuticals and medical devices.

You represent Infarmed in this negotiation with Boehringer Ingelheim Portugal, the Portuguese affiliate of Boehringer Ingelheim, relative to the launch of *Arritmolus* in Portugal.

The Portuguese national health system (*SNS*) reimburses, i.e., pays for, a certain percentage of the full price of an approved drug, according to its specific category. The reimbursement rates are not negotiable, they are predefined on a legal basis. Because *Arritmolus* fights a chronical cardiovascular disease, it is considered a group B drug. This group is reimbursed by 69 % of the price. Infarmed demands proof of short-term results from any drug applying for reimbursement.

Drug prices are always regulated. You must negotiate the public price (PP) for *Arritmolus* with Boehringer Ingelheim Portugal. This price is constrained by an upper limit (*price ceiling*) which is defined by existing legislation, based on an international referral system. It is given by the average price of the same drug in Portugal's reference countries – Spain (75 €), France (85 €), and Italy (80 €) –, i.e., 80 €.

In addition, the upper limit that Infarmed is allowed to negotiate is constrained by budget limitations. Financial constraints and the increasing medicine consumption have exerted a tremendous amount of pressure on Infarmed to comply with cost reduction policies. Therefore, whilst trying to negotiate the best conditions possible, Infarmed can never exceed an 8 M€ annual budget. Because Infarmed's analysts predict an annual demand of 200,000 units, their calculations for the impending contract, with an 8 M€ annual budget and a 69% reimbursement rate, drive down Infarmed's *price ceiling* as follows:

$$price\ ceiling = \frac{annual\ budget}{reimbursement\ rate * annual\ demand} = \frac{8{,}000{,}000}{0.69 * 200{,}000} = 57.97\ €.$$

Given that the current spending with the standard therapy is 3 M€, reimbursing *Arritmolus* at this public price would mean incurring in 5 M€ of incremental costs.

There are, however, incremental benefits as well. *Arritmolus* will reduce the number of hospital admissions, their duration and associated costs. Infarmed's analysts believe this will translate to 2 M€ of incremental benefits in terms of savings. There are other potential benefits (such as the reduction of the absenteeism rate) but they are extremely hard to quantify.

Recently, cardiac arrhythmia has been deemed one of the country's top health priorities. The Portuguese Health Ministry has issued a new directive to hasten the implementation of solutions. Given this, and knowing that superior drugs that attend to this affliction are currently being developed, Infarmed appreciates the importance of negotiating the market access of a new drug.

You have met for the first time with your counterpart last week. There was a bitter discussion that led you nowhere closer to an agreement, apart from the other negotiator having inadvertently leaked the high expectations of Boehringer Ingelheim Portugal for the price: 80 €. Having collected yourselves, you arranged to meet again tomorrow and come to a conclusion on, at least, the price of the drug and the value of pharmaceutical expenditure to be borne by the national health system.

Confidential Information of Boehringer Ingelheim Portugal

Boehringer Ingelheim is one of the world's leading pharmaceutical companies. It has just developed *Arritmolus*, a promising new drug for outpatient care. This drug suppresses cardiac arrhythmia, a chronic cardiovascular disease, and prevents its symptoms and complications. The new drug has already received regulatory approval in Europe from EMA (European Medicines Agency), following an assessment of its quality, safety and efficacy. The company is now looking to obtain market access, i.e., to be able to start selling their medicine. This will be accomplished by first negotiating price and reimbursement terms with the health regulatory bodies of the different countries. Infarmed is the Portuguese health authority.

You represent Boehringer Ingelheim Portugal, the Portuguese affiliate of Boehringer Ingelheim, in the negotiations with Infarmed relative to the launch of *Arritmolus* in Portugal.

Developing a new drug is a complex endeavor requiring significant investments. It takes about 12 to 15 years from discovery to the approved medication, sometimes entailing investments of more than 1 B€. The company needs to ensure that the revenues deriving from their newly approved medicine are sufficient to cover not only the costs associated with the development of that drug, but also the costs of all the other medicines that failed during the process, thus allowing the company to sustain its R&D investment levels – an impressive allocation of about 23 % of total capital, following its motto "Value Through Innovation" – and be profitable. Reaching an advantageous deal with Infarmed is of paramount importance to the financial sustainability of Boehringer Ingelheim Portugal.

The Portuguese national health system (*SNS*) reimburses, i.e., pays for, a certain percentage of the full price of an approved drug, according to its specific category. The reimbursement rates are not negotiable, they are predefined on a legal basis. Because *Arritmolus* fights a chronical

cardiovascular disease, it is considered a group B drug. This group is reimbursed by 69 % of the price.

Drug prices are always regulated. You must negotiate the public price (PP) for *Arritmolus* with Infarmed. This price is constrained by an upper limit (*price ceiling*) which is defined by existing legislation, based on an international referral system. It is given by the average price of the same drug in Portugal's reference countries – Spain (75 €), France (85 €), and Italy (80 €) –, i.e., 80 €. The analysts of Boehringer Ingelheim Portugal predict an annual demand of 125,000 units. Because Portugal is one of Turkey's countries of reference, and Turkey represents a large market, you were expressly prohibited by corporate headquarters to negotiate a price bellow 70 €.

The new drug presents incremental benefits relative to the standard therapy. *Arritmolus* will reduce the number of hospital admissions, their duration and associated costs. The analysts of Boehringer Ingelheim are extremely confident about the efficiency of *Arritmolus*. They believe this will translate to 6 M€ of incremental benefits for Infarmed in terms of savings. There are other potential benefits (such as the reduction of the absenteeism rate) but they are extremely hard to quantify.

Recently, cardiac arrhythmia has been deemed one of the country's top health priorities. Infarmed would value a new drug that could fight this affliction and show positive results from the start. However, obtaining proof of short-term results (i.e., conducting post-authorization updates) would cost Boehringer Ingelheim Portugal 1 M€.

You have met for the first time with your counterpart last week. There was a bitter discussion that led you nowhere closer to an agreement, besides you having inadvertently leaked your expectations for the public price of *Arritmolus*: 80 €. Having collected yourselves, you arranged to meet again tomorrow and come to a conclusion on, at least, the price of the drug and the value of pharmaceutical expenditure borne by the national health system.

Part B: Teaching Note

Case Synopsis

This case mimics price and reimbursement negotiations between pharmaceutical companies and national health authorities, relative to the launch of a new drug. The case study aims to provide a real-life negotiation simulation to be used in negotiation analysis courses, both in master programs and in executive education workshops. The work project focuses on the possibility of value creation – increasing the zone of potential agreement (ZOPA) – through the elaboration of package deals and contingent contract clauses. In fact, if merely a single-issue and value claiming agenda is pursued, the ZOPA is nonexistent. This will potentially cause friction between negotiating parties. The case also reflects upon the management of the negotiation process, and how to manage the differing expectations of the negotiating parties.

The negotiation variables are the public price (PP), the annual demand (annual number of drug units sold), the value of pharmaceutical expenditure to be borne by the national health system, the value of incremental benefits of reimbursing the new drug, and potential contingency clauses.

There are different expectations amid negotiating parties in what concerns the public price of the drug. This is directly correlated with the divergent expectations for the number of sold units (annual demand of drug units) and the resulting value of incremental costs or the value of pharmaceutical expenditure. Other differing expectations relate to the value of incremental benefits – cost savings in hospital admissions, their duration and all the associated expenditures.

In this situation, we can observe potential drivers of an escalation of conflict: if negotiators haggle over positions on price independently, then there is no ZOPA. Adding to this, a previous meeting is said to have strained the relation.

Discussion Questions

How to Manage the Negotiation Process?

In the words of James K. Sebenius, "negotiators often forget that the deal-making process can be as important as its content. […] Considerable academic research confirms […] process counts. What's more, sustainable results are more often reached when all parties perceive the process as personal, respectful, straightforward, and fair" (Sebenius 2001, 90).

Interpersonal processes and tactics common barriers are interpersonal issues, poor communication, "hardball" and attitudes (Lax and Sebenius, 3-D Negotiation: Playing the Whole Game 2003). Discussing bad negotiation practice, Sebenius highlights six broad classes of recurring errors: neglecting the other side's problem; letting price bulldoze other interests; letting positions drive out interests; searching too hard for common ground; neglecting BATNAs; failing to correct for skewed vision (Sebenius 2001).

Two important and differing views of the negotiation process are Fish and Uri's *principled negotiation*, and Thomas Shelling's *tacit bargaining*. Principled negotiation is a search for a broad framework that will justify detailed agreements, with an emphasis on rational argumentation and principled decision-making (numerical patterns are irrelevant, and concessions are jumps from one criteria of justification for a figure to another). With tacit bargaining, the "convergence of expectations lies at the heart of any bargaining process, and it is largely driven by non-verbal clues embedded in the factual situation itself rather than by explicit verbal arguments made by the parties" (Dierickx 2008, 16).

Fish and Uri's advice for the negotiation process come down to four simple points (simple in theory, at least): separate the people from the problem (be soft on people, hard on the problem); focus on interests, not positions; invent options for mutual gain; insist on using objective criteria (Fisher, Ury and Patton 2011).

Dierickx's alternative to an argumentative approach to negotiation is to "view verbal exchanges between the parties a *lubricant* of the negotiation process rather than as its engine". His prescriptive solution for the negotiation process is to obtain information about the other side's reservation price (*probing*), manage our opponent's beliefs about our own reservation price (*signalling*), identify the most likely candidates for a negotiated agreement (*focal points*), find ways to 'dig in' and resist demands for concessions (*commitment*), and make it easier for our opponent to concede (*maintain a courteous negotiating climate*) (Dierickx 2008, 14-15).

To go from merely effective to superior negotiation, you need to "face what is truly the right problem. You have focused on the full set of interests of all parties, rather than fixating on price and positions. You have looked beyond common ground to unearth value-creating differences. You have assessed and shaped your BATNAs. You have taken steps to avoid role biases and partisan perceptions. In short, you have grasped your own problem clearly and have sought to understand and influence the other side's such that what it chooses is what you want" (Sebenius 2001, 95).

The management of the negotiation process has implications in the long term because you might have to deal with the same party again. Even if you don't, for your interests to be met, the other side will still have to live up to his end of a current deal. Another long-term issue is your reputation: future negotiations may be affected by the way you negotiate this agreement.

How to Manage Different Expectations?

Differences in expectations may prove to be perilous in negotiations. The problem with biased estimations about the outcome (the usual cause of such differences) is that they tend to close the zone of potential agreement, lowering chances for the parties to reach an agreement.

Because of the different expectations comprehended in this case study, initially, a deal will not appear to offer enough value to both sides. This depicts the common barriers in *deal design* (value and substance – the second dimension of Lax and Sebenius' 3-D negotiation template): the lack of feasible or desirable agreements.

Lax and Sebenius' solution is to "go back to the drawing board to design deals that unlock value that lasts. […] Does some sort of trade between sides make sense and, if so, on what terms? Should it be a staged agreement, perhaps with contingencies and risk-sharing provisions?" (Lax and Sebenius, 3-D Negotiation: Playing the Whole Game 2003, 2).

Elaborating contingent contract clauses is useful to deal with differences in beliefs. They also provide liquidity to markets, create expected value. Other functions include insurance, lower costs, incentives, and signaling. When dealing with uncertainty, the help of outside experts could also prove to be an important tool. Be cautious, however, because "people are notoriously vague when describing uncertainty. […] Using numerical probabilities pushes decision makers to work harder on evaluating risk, and it tends to reduce misunderstanding between advisers and advisees." You should, then, speak the *language of probability*. In a "sophisticated analysis it is customary to run sensitivity studies, letting the more controversial numbers roam over plausible ranges" (Raiffa, Richardson and Metcalfe 2003, 133-148).

A critical uncertainty in this case study is the number of drug units that will be sold. To deal with this, Boehringer Ingelheim could propose a contingency clause that caps the number of annual drug units to be reimbursed by the national health system, and take full responsibility for any "extra"

units. This could also be negotiated in terms of a maximum pharmaceutical expenditure to be borne by the national health system. If the predefined budget for reimbursement was depleted, then Boehringer Ingelheim Portugal would be accountable for any drug unit sold from that point. As such, the company could demand higher prices for the drug.

Another important uncertainty concerns the value of incremental benefits provided by the adoption of the new drug. Contingency clauses could be developed to protect and benefit both Boehringer Ingelheim Portugal and Infarmed. If the value of cost saving in hospital admissions, their duration and all the associated costs was lower than a certain number, the pharmaceutical company could be held accountable and have to repay Infarmed in some way. This could entail previously determined fees, or even changing the contract terms to a more advantageous deal for Infarmed. On the other hand, the negotiating parties could agree to a contingency clause concerning a value of incremental benefits after which Infarmed would reward Boehringer Ingelheim Portugal. The pharmaceutical company could be rewarded with an increase of the public price of the drug, an increase in the number of drug units to be reimbursed, compensation payments, or in any other way deemed acceptable, viable and agreed upon by both parties.

How to Develop Package Deals?

A key hurdle to reach an agreement in this negotiation is that without changing the structure of the problem there is no zone of potential agreement, since the buyer's (Infarmed's) reservation price is 150 € and the seller's (Boehringer Ingelheim's) is 160 €. If the negotiating parties tackle the price of the drug as an isolated issue, they won't be able to successfully reach a deal.

The problem with following a single-issue framework is that parties take extreme positions and in the process often reach an impasse. They engage in excessive argumentation, irritating each other, creating resistance and throwing away information by not listening. It could even lead them to dispense explicit threats and punishments, a detrimental process that results in an escalation of conflict.

Hindrances that inhibit the inventing multiple options include "premature judgment; searching for the single answer; the assumption of a fixed pie [negotiations often appear to be fixed-sum games]; thinking that *solving their problem is their problem* [shortsighted self-concern leads a negotiator to develop only partisan positions, partisan arguments, and one-sided solutions]" (Fisher, Ury and Patton 2011, 31). Viewing the world through adversarial spectacles, with a zero-sum mentality, leads negotiator to neglect "elements of potential cooperation and collaboration […] because the parties are concentrating exclusively on the strictly competitive aspects of the problem" (Raiffa, Richardson and Metcalfe 2003, Part III).

The general solution is to also pursue value creation strategies, alongside value claiming. Value creation, or integrative bargaining, consists of increasing the ZOPA. This is accomplished by changing the very structure of the problem at hand – generate multiple issues by adding and dividing, to explore complementarities and synergies. Ask questions that focus on relative valuation, and think about "what outside issues might be highly valued if they were incorporated in the process" (Lax and Sebenius, 3-D Negotiation: Playing the Whole Game 2003). The general

solution is to also pursue value creation strategies, alongside value claiming. Value creation, or integrative bargaining, consists of increasing the ZOPA. This is accomplished by changing the very structure of the problem at hand – generate multiple issues by adding and dividing, to explore complementarities and synergies. Ask questions that focus on relative valuation, and think about "what outside issues might be highly valued if they were incorporated in the process" (Fisher, Ury and Patton 2011).

Instead of arguing, ask questions to help uncover the underlying shared and differing interests (probe behind positions). Don't haggle over isolated issues; establish linkages instead (*you scratch my back and I'll scratch yours*). And finally, agree on the package as a whole, not on separate issues.

For this specific case, we could propose the number of drug units to be financed by the national health system as an issue up for discussion (i.e., a negotiation variable), and negotiate it and the price of the new drug price simultaneously. This alone could have powerful implications in the negotiation.

The establishment of linkages between issues is an important potential driver of progress in this negotiation. Tying issues like the realization post-authorization updates (attaining proof of short-term results) by Boehringer Ingelheim Portugal and the maximum financial expenditure to be borne by the national health system, linking the value of incremental benefits from the adoption of the new drug to compensation policies, and combining any other issues in different ways could unlock value for the parties or help the negotiation move forward. After all possible links are established, the negotiators agree on all of them simultaneously, as a package deal. This is another dimension of negations where they prove to be more a form of artistry than an exact science.

Following these prescriptive measures would help the parties grasp untapped potential when negotiating, and ultimately enable them come to an agreement. Nonetheless, we must observe

"there is a tension between the tactics used to create a larger pie and those used to claim a larger portion of the pie created. How to balance this tension is part of the science and art of negotiation." (Raiffa, Richardson and Metcalfe 2003, 191). "At the end of the day, you want to create all possible value jointly, claim a full share of it, and prevent yourself from being exploited by a value-claimer" (Lax and Sebenius, 3D Negotiation: Powerful Tools to Change the Game in Your Most Important Deals 2006, 205).

Bibliography

Adamski, Jakub, Brian Godman, Gabriella Ofierska-Sujkowska, Bogusława Osińska, Harald Herholz, Kamila Wendykowska, Ott Laius, et al. 2010. *Risk sharing arrangements for pharmaceuticals: potential considerations and recommendations for European payers.* June 7. Accessed November 2017. https://bmchealthservres.biomedcentral.com/articles/10.1186/1472-6963-10-153.

Black, Ken. 2017. *What is a Drug Reimbursement?* October 18. Accessed November 2017. http://www.wisegeek.com/what-is-a-drug-reimbursement.htm.

Boehringer Ingelheim. 2017. *Boehringer Ingelheim: Drug Discovery Process.* Accessed November 2017. https://www.boehringer-ingelheim.com/drug-discovery/drug-discovery-process.

—. 2017. *Who We Are: Our Company.* Accessed November 2017. https://www.boehringer-ingelheim.com/who-we-are/our-company.

CarrotPharma. 2016. *What is Market Access?* Accessed November 2017. https://www.carrotpharma.co.uk/what-is-market-access.

Colasante, Walter. 2015. *Pricing & Market Access Outlook 2015/2016 Edition.* IMS Consulting Group, 26-34.

Dawson, Simon, and Elliot Rosen. 2017. *Market Access in practice: do you have a strategy?* Accessed November 2017. https://www.pharmafield.co.uk/features/2008/11/Market-Access-in-practice-do-you-have-a-strategy.

Dierickx, Ingemar. 2008. *Price Negotiations: The Distributive Dimension of Bargaining.*

European Commission. 2017. *EU health policies.* November. Accessed November 2017. https://ec.europa.eu/health/policies/policy_en.

European Medicines Agency. 2016. *Pharmacovigilance: post-authorisation.* Accessed November 2017. http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001819.jsp&mid=WC0b01ac05800241de.

—. 2017. *Post-authorisation safety studies (PASS).* Accessed November 2017. http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000377.jsp&mid=WC0b01ac058066e979.

Finn, Michael. 2016. *2016 Top Markets Report: Pharmaceuticals.* International Trade Administration, U.S. Department of Commerce, Industry & Analysis (I&A).

Fisher, Roger, William Ury, and Bruce Patton. 2011. *Getting to Yes: negotiating an agreement without giving in.* Third edition, revised edition. New York: Penguin Books.

Infarmed. 2015. *Monitorização mensal do consumo de medicamentos no ambulatório do SNS.* Direção de Informação e Planeamento Estratégico, Infarmed, INFARMED, I.P.

Kaitin, K. 2010. *Deconstructing the Drug Development Process: The New Face of Innovation.* Accessed November 2017. http://doi.org/10.1038/clpt.2009.293.

Kogels, Eline. 2009. *The Emerging Hurdles For Reimbursement And Market Access For New Innovative Pharmaceuticals.* September. Accessed November 2017. https://www.ispor.org/news/articles/Sept09/EHFR.asp.

Lax, David A., and James K. Sebenius. 2006. *3D Negotiation: Powerful Tools to Change the Game in Your Most Important Deals.* Boston, MA: Harvard Business School Press.

—. 2003. "3-D Negotiation: Playing the Whole Game." *Harvard Business Review*, November 01.

Ministério da Saúde. 2015. "Portaria n.º 195-D/2015." *Diário da República Eletrónico.* June 30. Accessed December 2017. https://dre.pt/home/-/dre/67644327/details/maximized?p_auth=xyvt9Atq.

—. 2016. "Portaria n.º 290-B/2016." *Diário da República Eletrónico.* November 15. Accessed December 2017. https://dre.pt/home/-/dre/75748125/details/maximized?serie=I&day=2016-11-15&date=2016-11-01.

Ministério da Saúde. 2011. *Portugal Pharmaceutical Country Profile.* Ministry of Health in collaboration with the World Health Organization.

Raiffa, Howard, John Richardson, and David Metcalfe. 2003. *Negotiation Analysis: The Science and Art of Collaborative Decision Making.* Cambridge: Harvard University Press.

Rose, Les. 2010. *Key factors for market access.* February 25. Accessed November 2017. http://social.eyeforpharma.com/evidence/key-factors-market-access.

Schoonveld, Ed, and Stefan Kloss. 2010. *Market access: Risk sharing and alternative pricing schemes.* August 10. Accessed November 2017. http://social.eyeforpharma.com/evidence/market-access-risk-sharing-and-alternative-pricing-schemes.

—. 2010. "Unpacking Risk Sharing and Alternative Pricing Schemes." *Pharmaceutical Commerce*, February 25.

Sebenius, James K. 2001. "Six Habits of Merely Effective Negotiators." *Harvard Business Review*, April: 87-95.

Stojaspal, Jan. 2012. *Market access: Pharma and the definition of value.* May 8. Accessed November 2017. https://social.eyeforpharma.com/evidence/market-access-pharma-and-definition-value.

The Economist Intelligence Unit. 2015. *Value-based healthcare in Portugal: Necessity is the mother of invention.* The Economist Intelligence Unit.

van Boxtel, Chris J., Budiono Santoso, and I. Ralph Edwards. 2008. *Drug Benefits and Risks: International Textbook of Clinical Pharmacology, Revised 2nd edition.* Amsterdam; Washington, DC: IOS Press and Uppsala Monitoring Centre.

Voisin Consulting Life Sciences. 2017. *Core reimbursement dossier.* Accessed November 2017. https://voisinconsulting.com/glossary/product-development-Regulatory-Strategy/core-reimbursement-dossier.

Wight, Colin. 2012. *The true meaning of market access?* September 26. Accessed November 2017. http://www.pmlive.com/pharma_intelligence/the_true_meaning_of_market_access_422511.

World Health Organization. 2015. *2015 Global Survey on Health Technology Assessment by National Authorities. Main findings.* Geneva, Switzerland: WHO Document Production Services.

—. 2017. *Health technology assessment.* Accessed November 2017. http://www.who.int/health-technology-assessment/about/Defining/en/.