Studies for risk sharing in high-cost medicines in supplementary health in Brazil*

Estudos para o compartilhamento de risco em medicamentos de alto custo na saúde suplementar no Brasil

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ABSTRACT

The new technologies are a reality of our historical time in all areas. In health, these technologies have multiplied at an accelerated pace through techniques, instruments for carrying out tests and procedures and, mainly, with drugs and implantable medical devices that are created to meet complex

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needs such as cancer treatment, serious or rare diseases. The high cost of these drugs and devices is justified by the industry as a result of investments made in research, but, for public and private paying sources it has been a dilemma, because resources are finite and shared among all system users. This work studies the feasibility of sharing risks between public and private payers and the pharmaceutical industry.

KEYWORDS

health — medicines — high cost — risk sharing agreement — finite resources

RESUMO

As novas tecnologias são uma realidade de nossa época histórica em todas as áreas. Na saúde, essas tecnologias têm se multiplicado de forma acelerada por meio de técnicas, instrumentos para realização de exames e procedimentos e, principalmente, de medicamentos e dispositivos médicos implantáveis que são criados para atender a necessidades complexas como tratamento oncológico, de doenças graves ou raras. O alto custo desses medicamentos e dispositivos é justificado pela indústria em decorrência dos investimentos realizados em pesquisa. Porém, para as fontes pagadoras públicas e privadas tem sido um dilema, porque os recursos são finitos. Este trabalho estuda a viabilidade do compartilhamento de risco entre fontes pagadoras públicas e privadas e a indústria farmacêutica.

PALAVRAS-CHAVE

saúde — medicamentos — alto custo — contrato de compartilhamento de risco — recursos finitos

1. Introduction

New technologies are a reality in all economic and social areas of contemporary life. They make living and working easier, stimulating new businesses, and enhancing efficiency in areas such as health, education and management. But for all they improve human interaction and relationships, they involve risks and costs not always compatible with financial budgets.

The cost of new technologies in healthcare is a concern around the world, even for leading economic powers such as the United States, Germany and England. In the United States, for example, in the last decade, spending on pharmaceutical products has more than tripled, from 40 to 140 billion dollars. And management costs have accounted for 50% of health spending.[1]

In Brazil the situation is no different. Data from the Instituto de Estudos de Saúde Suplementar (IESS) published in May 2022 shows that the increase in medical and hospital costs (VCMH) was 27.7% between September 2020 and September 2021, significantly higher than the inflation rate, which was around 10%.[2]

Increased longevity, advance of digital technologies in the health sector and inefficient, wasteful usage, are seen as the main causes of the exponential rise in health costs around the world.

Despite the positive expectations that usually accompany the emergence of new technologies or medicines, experience shows that the new is not always the best or the safest. At the same time, the market values of high-cost medicines do not allow for margins of error, involving, as they do, millions of dollars. Zolgensma, used to treat the effects of muscular atrophy in infants, is valued at 2.1 million dollars; Luxturna, for hereditary retinal dystrophy, at 850 thousand dollars; Ravicti, to prevent the accumulation of ammonia in the blood of patients with urea cycle dysfunction, 793 thousand dollars; and Spiranza, also for muscular atrophy, $61,000.[3]

The high prices of medicines drive the search for alternatives which, far from simple, are necessary for technology to be incorporated safely, protecting the sector from potential machinations of the pharmaceutical and medical supply industries, and, above all, so that the resources administered by public and private healthcare are enough for the provision of general healthcare, not only complex and costly procedures.

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1 RIBAS-FILHO, Jurandir Marcondes. O porque dos altos custos na área médica e da saúde. ABCD—Arquivos Brasileiros de Cirurgia Digestiva, São Paulo, v. 24, n. 3, p. 189-190, 2011. Available at: https://doi.org/10.1590/S0102-67202011000300001. Accessed on: 20 Sept. 2022.

2 VARIAÇÃO dos custos médico-hospitalares supera inflação: entenda motivos e impactos. TV Senado. Rio de Janeiro: Senado Federal, 27 de maio, 2022. TV program. Available at: https://www12.senado.leg.br/tv/programas/cidadania-1/2022/05/variacao-dos-custos-medico-hospitalares-supera-inflacao-entenda-motivos-e-impactos. Accessed on: 26 Sept. 2022.

3 REMÉDIOS de milhões: quais os medicamentos mais caros do mundo? UOL, 5 July 2022. Available at: https://www.uol.com.br/vivabem/noticias/redacao/2022/07/05/remedios-de-milhoes-quais-sao-os-medicamentos-mais-caros-do-mundo.htm. Accessed on: 26 July 2022.

Thus, in this study we analyze the legal and economic aspects of the risk sharing approach to medicines. The methodology has been studied in various countries, and implemented in some practical experiments. Studies focus on medicine risk-sharing practices used in countries such as Italy, Portugal, Lithuania, the Czech Republic, the Netherlands, Sweden and the United Kingdom.[4] We also consider the Brazilian scenario, in particular the bill which provides for its use in Sistema Único de Saúde (SUS).

The hypothesis is that assessment of health technologies is enhanced by sharing risk between funding entities—public or private—and the pharmaceutical industry, so economic resources are used rationally and the industry benefits from a fair return on investment in health product research.

Risk sharing can reinforce the efficiency and effectiveness of medicines, assessed, as they are, in the real world after the obligatory clinical research.

A bibliographic review method, using the Scopus and Google Scholar platforms, was utilized.

2. Risk sharing in the Health Sector

Public and private health resource planning and strategy in Brazil has different features from that found in other countries. Brazil, according to Lottenberger et al., "ages like Sweden, dies like Syria and gets sick like South Africa".[5] The arises from the fact that, according to data cited, we bear the weight of a triple burden: chronic diseases (high blood pressure, diabetes, heart disease and others); an aging population; epidemics such as malaria, dengue, Zika, Chikungunya and other infectious diseases; and high rates of deaths and accidents due to violence and traffic accidents.

This situation impacts costs and increases governance requirements to manage resources. At the same time, there is a high demand to treat serious and rare diseases, for which medications are almost always expensive.

Strictly speaking, all these needs must be met, since rights and access should be equal, for elderly people, people with chronic or infectious diseases or

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[4] FERRARIO, Alessandra; KANAVOS, Panos. Managed entry agreements for pharmaceuticals: the European experience. EMiNet, Brussels, 2013.

[5] LOTTENBERG, Cláudio; SILVA, Patrícia Ellen da; KLAJNER, Sidney. A revolução digital na saúde. São Paulo: Editora dos Editores, 2019. p. 14.

with rare or congenital diseases. The public and private systems must provide adequate funds to pay for the many treatments required.

The high cost of medicines is partly due to the safety requirements of clinical research, the results of which can take many years. After the pre-clinical phase or phase zero, conducted in the laboratory, focused on identifying benefits and risks, there are three other phases before the medicine is introduced onto the market, in phase IV, also called pharmacovigilance. At this point, the product is made available for consumption and its effects are monitored and analyzed. In phase IV, unforeseen side effects or adverse results not detected in previous phases may be identified. Phase IV monitoring is aimed at safer use of the medicine, medical interactions and evaluation of therapeutic effects on an expanded scale, leaving aside follow-up assessments made in previous research phases.[6]

Innovation in medicine is driven by massive pharmaceutical industry investment, given the expensive and lengthy research and development process before products are launched on the market. The costs are direct and indirect since, in addition to funding, it is necessary to consider the opportunity cost, i.e., the returns the money used in research would yield if invested in the financial market.[7]

New products on the market still cause uncertainty in terms of efficiency, effectiveness, appropriacy, safety and an improvement in relation to similar medicines, used for the same pathology. In other words, the risks associated with the use of the medicine are not fully mapped and addressed, in terms of side effects or the effectiveness, making it hard to determine the cost benefit. As Denizar Vianna Araújo explains, cost-effectiveness analysis is "the best option when comparing two or more treatments. […] Health intervention is said to be cost-effective if it produces a clinical benefit justifiable for its cost".[8]

At this point in the clinical research, when the medicine is already on the market, risk or cost sharing agreements may be implemented as a way of collecting new data, and to specify the amounts to be spent.

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6 PEREIRA, Paula Moura Francisconi de Lemos. Responsabilidade civil nos ensaios clínicos. Indaiatuba: Foco, 2019.

7 BARROS, Pedro Pita. Economia da saúde: conceitos e comportamentos. 4. ed. Coimbra: Almedina, 2019. p. 382.

8 ARAÚJO, Denizar Vianna. Custo na saúde. In: CARVALHO, Marinilza Bruno de. Inovação em saúde: uma nova era. Rio de Janeiro: Ciência Moderna, 2019. p. 73.

For Garrison et al.,[9] there is significant and growing interest among funders and manufacturers in agreements involving payment for performance or risk sharing. Known as "performance risk sharing agreements" or performance based risk sharing arrangements (PBRSA), this arrangement involves "a plan whereby product performance is tracked in a defined patient population over a specified period and fiancial support is based on the health and cost of results achieved".[10] The agreement aims to reduce uncertainty arising from the increased evidence collection during the use of the medicine among a population predetermined by the funding entity.

Vianna, Sachetti and Boaventura define the risk sharing agreement as that in which "the State supports access to a new treatment, while the pharmaceutical industry agree to receive payment for the product according to performance in real conditions". The key point is to define the elements that will determine the percentages of risk sharing, which will always be complex, as it depends on "the collection of additional evidence that may refer to therapeutic benefits or the number of patients, according to evaluation of use in practice".[11]

For Gonçalves et al., this can:

> (a) mitigate uncertainty about the clinical outcomes and cost-effectiveness of medicines by allowing conditional funding, depending on the collection of additional evidence in the decision-making process, (b) link funding or payment to the outcomes in the context of clinical practice, (c) restrict drug use to a subpopulation of patients through selection or eligibility criteria where most effective, and (d) manage budgetary impact.[12]

Sharing forms part of a broader context in which public and private systems face increasingly high healthcare costs,[13] with no sign of abating, since in the

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9 GARRISON JR., Louis P. et al. Performance-based risk-sharing arrangements: good practices for design, implementation, and evaluation: report of the ISPOR good practices for performance-based risk-sharing arrangements task force. Value in Health, v. 16, p. 703-719, 2013. Available at: https://pubmed.ncbi.nlm.nih.gov/23947963/. Accessed on: 4 June 2023.

10 Ibid., p. 704, free translation.

11 VIANNA, Denizar; SACHETTI, Camile Giaretta; BOAVENTURA, Patrícia. Acordo de compartilhamento de risco: projeto piloto no Sistema Único de Saúde. Jornal Brasileiro de Economia da Saúde, v. 14, supl. 1, p. 102, 2022.

12 GONÇALVES, Francisco R. et al. Risk-sharing agreements, present and future. Ecancermedicalscience, v. 10, no. 12, p. 823, apr. 2018. DOI: 10.3332/ecancer.2018.823. PMID: 29743943; PMCID: PMC5931811.

13 INSTITUTO DE ESTUDOS DE SAÚDE SUPLEMENTAR (IESS). 26º VCM/Iess, ago. 2022. Série Histórica da Variação do Custo Médico-Hospitalar. Available at: https://www.iess.org.br/vcmh/26o-vcmhiess. Accessed on: 28 Sept. 2022.

health area, technologies almost always supplement, rather than exclude, each other; furthermore, there is an asymmetry of risks between the public and private funding and the pharmaceutical industry. Risk sharing to define funding more conducive to results can lend greater rationality to price setting and financial decision-making.

Santos notes that

> […] the pharmaceutical industry bases its activities on the search for profit, adopting as one of its permanent growth strategies a marketing appeal to consumerism, launching new technologies that, although expensive, do not always translate into effective improvements or innovations in the treatment of the most diverse diseases.[14]

In the author's view, there is no certainty that new medicines are actually better than their predecessors or similar ones available on the market.

When it comes to serious or rare diseases, marketing is largely unnecessary, as the prospect of improving patient quality of life, or delaying symptoms, and thus prolonging survival is enough, regardless of costs and effectiveness, which may not even be a consideration.

Claus Møldrup uses the concept of rational pharmacotherapy to support the use of risk sharing. Rational pharmacotherapy is defined by the author as "drug treatment that provides the greatest effect with the least serious and the fewest side effects at the lowest possible price". The author offers an equation to explain the idea: "effect (clinical studies) + extent of side effects/price = extent of rational pharmacotherapy".[15]

Møldrup elaborates the concept:

> A large proportion of all prescribed medications do not have the desired medical effect. The many explanations include poor drug choice, genetic factors, interactions, improper usage, and poor drug quality. A no-cure, no-pay approach can combat these problems, optimizing the effect, while making the treatment economically viable. If the medicine

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[14] SANTOS, Bruno Henrique Silva. Acordos de compartilhamento de riscos para incorporação de tecnologias em saúde pelo SUS: normas jurídicas aplicáveis e análise do caso do nusinersena. Revista de Direito Público da Economia—RDPE, Belo Horizonte, ano 17, n. 67, p. 70, jul./set. 2019.

[15] MØLDRUP, Claus. No cure, no pay. BMJ, v. 28, no. 330(7502), p. 1,262, May 2005. DOI: 10.1136/bmj.330.7502.1262. PMID: 15920131; PMCID: PMC558101.

> does not cure, alleviate, or prevent the symptoms based on specific clinical measures or visible results, the healthcare system and the patient get their money back. A money-back guarantee may also apply if the patient experiences adverse effects. This is the unprecedented dimension of rational pharmacotherapy.[16]

A simple concept, backed by staightforward logic of no result, no payment has highlighted the numerous obstacles which need to be overcome in applying the risk sharing model involving consumers and medicine suppliers.

Examining risk sharing experiences in other countries informs a critical analysis of this system.

2.1 Theoretical foundation of risk sharing in light of the Theory of Stakeholders

The starting point of the Theory of Stakeholders is the proposition that the interests of society are maximized if companies, in any economic sector, reward all interactions, not just those of shareholders. Generating value for different stakeholders, not just for shareholders, will depend on the method of action defined by the company.[17]

The debate about the main purpose of companies offering goods and services, and the the type of relationship they need to establish with the interested parties, became more intense in the 1980s and 1990s.[18] Economic entities were to be judged not only by shareholder and investor´profits, but by the value generated for stakeholders and for affirmative action in the area of social responsibility.

The expectation is that companies benefit all interested parties internally and externally, not only in terms of economic value, but ethical, social and environmental, through transparent and reliable governance.

Freeman[19] pioneered the study of the Theory of Stakeholders. Since then, research has progressed and, in the 1990s, two aspects were distinguished,

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[16] Ibid., p. 1,262.

[17] JENSEN, Michael C.; MECKLING, William H. [2001.] Theory of the firm: managerial behavior, agency costs and ownership structure. Journal of Financial Economics, v. 3, no. 4, p. 307, 1976.

[18] MITCHELL, R.K. et al. Toward a theory of stakeholder identification and salience: defining the principle of who and really counts. Academy of Management Review, Ada, v. 22, no. 4, p. 853-886, 1997.

[19] FREEMAN, RE. Strategic management: a stakeholder approach. Boston: Pitman, 1984.

both of interest here: the management of stakeholder value and the ethical decisions of administrators in balancing the diverse interests of internal and external stakeholders.[20]

Prior to the Theory of Stakeholders, the notion prevailed that the sole objective was commercial, to satisfy the financial interests of its shareholders.[21] This can be seen in the Theory of the Firm, originating in the 18th century, with Adam Smith in the work The wealth of nations, published in 1776.

Ronald Coase, among others, expanded reflections on the Theory of the Firm in 1960 with his seminal article on the problem of social cost.[22] In his conclusion, he states that property rights, including property used as an instrument of economic production, cannot be unlimited and that, "in designing and choosing between social arrangements, we must envision the total effect".[23]

Including the full effect in social arrangements and implementing of ownership rights provides a new conception of economic production, but not only that. A company, in accordance with the Theory of Stakeholders, must generate value for all those linked to it, whether internally, for employees and service providers, or for consumers, production chain suppliers, government, state bodies and society.

Barakat et al. further this reflection with the idea of the legitimacy of stakeholders:

> Pfeffer and Salancik (1978), meanwhile, developed an "organization-environment" interaction model, framing the effectiveness of an organization in terms of management of demands, especially those of interested parties. On the challenge of determining which stakeholder deserves more consideration in the decision process, Carroll (1991) identified two elements: legitimacy and power. The author states that, from a moral perspective, legitimacy may be more important, but from a managerial viewpoint, power is the central influence. Carroll (1991)

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[20] TEIXEIRA NETO, José Maria Franco. Uma revisão da teoria dos stakeholders e principais pontos de controvérsias. Revista Brasileira de Administração Científica [Brazilian Journal of Scientific Administration], v. 10, n. 2, abr./jun. 2019.

[21] BOAVENTURA, João Maurício Gama. Dominância de stakeholders em empresas brasileiras: contribuições à teoria dos stakeholders. 2012. 117 f. Tese (livre-docência)—Faculdade de Economia, Administração e Contabilidade, Universidade de São Paulo, São Paulo, 2012. DOI: 10.11606/T.12.2013.tde-17122013-090933. Accessed on: 28 July 2022.

[22] Ibid., 2012.

[23] COASE, RH The problem of social cost. The Journal of Law and Economics, v. 3, Oct. 1960. Available at: https://www.journals.uchicago.edu/doi/10.1086/466560. Accessed on: 4 June 2023.

> observes that legitimacy refers to the extent to which a group has a justifiable right to make claims. For example, a group of 300 employees who are to be laid off due to a plant closure have a greater claim on management attention than the local chamber of commerce, which is focused on loss of taxes paid by the company.
> […]
> Neville, Bell and Whitwell (2011, p. 369) believe that only the moral factor of legitimacy should be considered, advancing the following definition: The moral legitimacy of stakeholder claims involves an assessment by managers of to what extent they exceed a desirable and appropriate threshold, within a personal, organizational and socially constructed system of ethical norms, values, beliefs and definitions.[24]

The work discusses the moral legitimacy of patients with serious or rare diseases who need high-cost medicines they cannot afford and thus must rely on organized and supplementary healthcare providers, promoting the case for stakeholders as beneficiaries of operator and medical industry actions.

Risk sharing in relation to high-cost medicines can help balance the interests of shareholders and stakeholders, leading to increased legitimacy.

3 Analysis of risk sharing experiences in England, Italy and Portugal

The prohibitive cost of medicines and resulting difficulties in organizing public and private budgets to meet universal needs are not unique to Brazil, nor restricted to countries with emerging economies. In leading economies the scenario is the same. There is a real concern about the increase in the number of medicines available and the high costs they add to public and private health budgets.

To this end, risk and cost sharing trials involving providers, and the pharmaceutical industry have been tried out in other countries. Here we present a bibliographical review of some recent studies on these experiences to understand and evaluate the difficulties and build a hypothesis to address them.

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[24] BARAKAT, Simone Ruchdi et al. Legitimidade: uma análise da evolução do conceito na teoria dos stakeholders. Revista de Ciências da Administração, v. 18, n. 44, p. 70, abr. 2016. Available at: http://dx.doi.org/10.5007/2175-8077.2016v18n44p66. Accessed on: 28 Sept. 2022.

3.1 England

England organizes its public health system around the National Health Service (NHS), based on the coordinated work of different public authorities with a technical opinion on the allocation of public resources to health provision. One of these authorities is the National Institute for Health and Care Excellence (NICE), a non-governmental health authority created by the Department of Health to promote quality health care provision.

Michael D. Rawlins[25] explains that Nice began in the 1990s, when the government and general population expressed concern about the NHS hospital system, which restricted patient access to new medicines considered excessively expensive. The beta-interferon medicine used to treat multiple sclerosis, some anticancer treatments and anti-psychotic medications have become a topic of public debate due to hospital practices. As the English health system is financed entirely by public taxes, pharmaceutical products are available to everyone, or to no one.

In December 1997, according to the author, the British government declared its intention to establish an institute of clinical excellence to

> […] advise the National Health Service on the use of individual of pharmaceutical products and other provisions (technology assessment) and to develop clinical guidelines so that healthcare professionals could provide (NHS) patients with the best quality of service possible. However, in developing the forms of guidance, the initiative had to consider both clinical effectiveness and cost-benefit.[26]

The author, Michael D. Rawlins, became the first president of Nice, in November 1998. In April 1999, it became a legal entity and began its work.

Over the years, with increasing concern about high-cost medicines, Nice has become a reference standard for many countries. Some have tried to implement a similar system, without success, according to Sean Tunis, former medical director of the US Centers for Medicare and Medicaid Services in the George W. Bush administration, speaking to the New York Times: "I spent a lot of time

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[25] RAWLINS, Michael D. National Institute for Clinical Excellence: nice works. Journal of the Royal Society of Medicine, v. 108, no. 6, p. 211-219, 2015. DOI: 10.1177/0141076815587658.

[26] Ibid., P. 213.

learning about Nice and trying to adopt the processes and mechanisms they use, and we just couldn't."[27]

Andrew Dillon,[28] Nice chief executive in 2009, stated that the organization is distinguished by its nature and form. It does not carry out health technology assessments; it collaborates with seven groups of universities with whom it has contracts managed by the NHS research and development directorate.

Also, according to Dillon, the role of Nice is to commission research and analyze results to advise the NHS on whether it should incorporate the technology and under what terms. Nice decisions are legally binding and used in NHS decision-making.[29]

It should be noted that Nice follows the controversial system Quality Adjusted Life Year (QALY), which clearly expresses the conflict between the pharmaceutical industry and the entities responsible for funding healthcare expenses.

QALY is defined in the glossary[30] of the International Network of Agencies for Health Technology Assessment (Inahta)[31] as "a unit of health care outcomes that assesses lifespan gains (or losses), according to quality of life, subsequent to a health care intervention". INHATA is a network of 50 agencies that conduct health technology assessment to support decision-making in health care systems. It serves 31 countries and its results affect the lives of around 1 billion people. Network members share evidence-based analysis reports on health procedures and events.

In the same glossary, INHATA states that "QALYs can provide a common unit for comparing cost-utility across different interventions and health problems". And:

> Quality-adjusted life year (QALY): a unit of health care outcomes that measures lifespan gains (or losses) subsequent to a health intervention according to quality of life. QALYs can provide a common unit for comparing cost-utility across different interventions and health problems.[32]

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[27] HARRIS, Gardiner. British balance benefit vs. cost of latest drugs. New York Times, 2 Dec. 2008. Available at: www.nytimes. com/2008/12/03/health/03nice.html?incamp=article_popular_5. Accessed on: 28 Sept. 2022.

[28] HAWKES, Nigel. Health technology assessment: Nice goes global. BMJ, v. 338, p. b103, 2009.

[29] EUROPEAN OBSERVATORY ON HEALTH SYSTEMS AND POLICIES. Health technology assessment and health policy-making in Europe: current status, challenges and potential. 2008. Available at: www.euro.who.int/Document/E91922.pdf. Accessed on: 28 Sept. 2022.

[30] HTA. Glossary.net. Available at: http://htaglossary.net/cost-per-QALY. Accessed on: 20 Oct. 2022. Free translation.

[31] INAHTA. The International Network of Agencies for Health Technology Assessment. [202-]. Available at: https://www.inahta.org/. Accessed on: 20 Oct. 2022.

[32] HTA, Glossary.net, op. cit., free translation.

In the English health system, QALY is a methodology used by Nice that, once applied to a new pharmaceutical product, for example, has a binding effect on the NHS, which is obliged to pay for it. Or, alternatively, it is exempt from this responsibility due to the result obtained in the QALY study.

But despite the well-organized cost-effectiveness assessment system and a service recognized worldwide for its technical quality, the risk-sharing project identified various problems that may accompany this strategy of incorporating high-cost medicines. It is still studied and referenced as a model of what should and should not be done when it comes to risk sharing.

Consider the risk sharing initiative of 2002 involving the English government and the companies Biogen Idec, Merck Serono, Schering AG (now Bayer Schering/Pharma) and Teva/Aventis, to fix medical prices based on an assessment of the concrete benefits to the patient. The proposal concerned the use of Interferon and Copaxone R in the treatment of multiple sclerosis, following rejection by Nice due to the high cost and uncertainty about the positive clinical results.

Renata Curi Hauegen notes:

> The price of treatment was initially set at £8,000 (eight thousand pounds) per patient per year, close to the value initially intended by the companies. The agreement determined a reduction in the price if clinical performance did not meet the determined criteria. The aim was for the price reduction to reach a cost per QALY of £36,000 (thirty-six thousand pounds). To promote balance in the cost-effectiveness relationship, price adjustments were planned for every 2 (two) years. To adapt the price according to performance, the parties agreed that the companies could, alternatively, refund the amount paid by the government or deliver the same quantity of medicine to another patient, at no cost to the State.
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> An initial period of 10 (ten) years was established for the agreement to become valid, during which time the government assumed the obligation to cover the costs of treatment for patients who participated in the program.[33]

[33] HAUEGEN, Renata Curi. Risk sharing agreements: acordos de partilha de risco e o sistema público de saúde no Brasil—oportunidades e desafios. Tese (doutorado)—Programa de Pós-Graduação em Políticas Públicas, Estratégias e Desenvolvimento, Instituto de Economia, Universidade Federal do Rio de Janeiro, Rio de Janeiro, 2014. p. 73.

Even though it was structured in accordance with the best governance standards, the project, according to its first report, had weaknesses: for example, the high cost of implementation given the extensive need for specialized labor, such as nursing. Three years were spent recruiting patients, when the initial planning had estimated 18 months.

Hauegen also highlights:

> Relevant information for outcome assessment was not considered, such as the impact on remission or the global impact on disease progression, a measure already established in the evaluation of the benefits of interferons. There was no record of the preparation and application conditions of the medication, frequency of remissions and progression of the disease during treatment, development of side-effects and neutralizing antibodies, duration of therapy, reasons for discontinuation of treatment and subsequent rate of progression. The scale used to measure the severity of the disease was limited to patient mobility, overlooking associated problems, such as fatigue and mental decline. […] The results of the effectiveness evaluation of the first report demonstrated that the clinical effects were weaker than expected, with a decline in the health of some patients, so that the price should decrease within the contract limit, or reach zero. The scientific council, however, […] decided to extend the technical evaluation without reducing the price, as it appeared hasty to conclude definitively whether the treatment was cost-effective. […] Since June 2010 there has been no news of published reports on the treatment, reinforcing the idea that the lack of evidence control is one of the negative points of the scheme.[34]

There are many criticisms of the model implemented in Britain, including characterization of the program as true risk sharing. Hauegen, in his research, concludes:

> It seems clear to us that the decision to extend the term removed the main element of the contract, i.e., the risk, as it guaranteed implementation of the technology until its results were approved. In our opinion, since the price was maintained, as with incorporation of the treatment itself, the contract, which was about sharing risk, had become a matter of purchase and sale.[35]

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[34] Ibid., p. 72.
[35] Ibid., p. 78.

These are essential aspects: defining the risk sharing period and the method of evaluating the clinical outcome. The obligations of the contracting parties in relation to the shared risk should always be identified, so that the contract does not lose its essential element: the existence of a risk and its consequences, shared by the parties.

The positive aspect of the English experience is that it was studied and analyzed by several researchers around the world, who contributed significantly to improving risk sharing for financing high-cost medicines.

In England a different strategy was used concerning the drug Ranibizumab, a treatment for macular degeneration, the object of a risk-sharing contract between the manufacturing company, Novartis and Nice operations.

Assessing the merits of the case and finding the cost to be very high, Nice and Novartis came to an agreement that provided for a dosage limit of 14 injections into the eye per patient paid for by the public authorities. Novartis was obliged, under the agreement, to deliver the medicine to the government at no cost if a greater number of injections per patient were necessary for the treatment to be effective. The laboratory could choose between providing the medicine for extra injections at no cost or offering a credit note to the government.

The agreement was beneficial for both parties and meant the manufacturer would have evidence of the number of injections needed for each patient to obtain the best result. Other European countries used this same agreement for medication, only varying the number of injections assumed as the financial responsibility of the public authorities.

For Hauegen,[36] however, this model cannot be classified as a risk-sharing contract in real terms, but only in terms of volume. It seems clear, however, that it is a risk-sharing contract, as the risk is present, in terms of quantity if not outcome. In fact, it may be stated that the limit is present in terms of the individualized result for each patient, since a ceiling of 14 injections was set and anything greater than this was to be covered by the manufacturer.

The risk was in the number of doses, not the single result, but was undoubtedly shared.

Other sharing models have been tried out in England, and, according to the research, the hypothesises is one of trial and error, always with the aim of improving contracts and adapting them to each different need, which could equally work in other countries, such as Brazil.

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[36] Ibid., p. 83.

3.2 Italy

Italy, also, has been exploring ways of rationalizing medication costs, through three types of agreement: direct discount, risk sharing and payment according to result.

For Hauegen, however, the difference between risk sharing and payment by result is illusory, as both have the same structure and essential elements: "establishing the price according to performance in real conditions, varying only regarding the value of the rebate or refund. The parties can share the risk in terms of performance and size".[37]

Italy has already carried out several risk-sharing experiments with dental treatments since 2006, and the results are positive, especially for patients, although there are criticisms and need for improvement. Hauegen highlights a key element that data sharing provides in the way it was adopted in Italy:

> Data collection is essential, to compare information offered by the pharmaceutical industry at the time of incorporation and clarify the administrative decision.
> It can offer benefits to everyone involved. Patients have timely access to innovative treatments, the industry can regain trust, and foster a better reputation, taking responsibility for the performance of its product.[38]

Italy has a medicine monitoring registry service used to collect data on practical use, an essential instrument in the adoption of risk-sharing contracts. This work is carried out by the Agenzia Italiana del Farmaco (Aifa), assisted by Comitato Prezzi e Rimborso (CPR) (Price and Reimbursement Committee), and the Commissione Tecnico Scientifica (CTS), (Technical-Scientific Commission). Besides evaluating the drug for entry into the health system, Aifa carries out, with the help of these bodies, continuous monitoring while the drug is on the market, evaluating the clinical, economic and social consequences of the product, through technology assessment reports.[39]

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[37] Ibid., p. 100.
[38] Ibid., p. 101.
[39] MELO, Valdete A.; ASCEF, Bruna O.; GIANFRATE, Fabrizio. Italy: a study case of medicines pricing and reimbursement. Brazilian Journal of Hospital Pharmacy and Health Services, v. 13, no. 2, p. 814, 2022. DOI: 10.30968/rbfhss.2022.132.0814.

The monitoring registry was initially established for oncology medicines, later expanded to medicines intended for orphan diseases, HIV, cardiovascular diseases, diabetes, cardiovascular and ophthalmological conditions.

Hauegen observes:

> The Medication Monitoring Registry is the most important instrument in structuring alternative medication management. It aims to track and evaluate patient selection criteria, collect epidemiological data, including information on safety, gather additional information not obtained during the first evaluation of the medicine and verify the use of the medicine in clinical practice, the latter being the most important element for the risk sharing contract.
> […]
> Pietro Gallo and Paola Deambrosis, of Aifa, add: the objectives of the Italian Medicine Registry are to monitor appropriate use of certain medicines and obtain information on the therapeutic value in real-life conditions. According to Angelo Pallozo, director of the pharmaceutical department at the Venetian Oncology Institute, Padua, Italy, the monitoring record and risk sharing arrangement made it possible to reconcile the high demand for high-cost effective medicines, offering access to medicines for which the economic and therapeutic value is still uncertain.[40]

Monitoring data on the use of medicines and their results for patients allows risk sharing to be structured with elements that ensure fairness and good faith between contracting parties.

3.3 Portugal

In Portugal, Decree-Law 195, 2006, established rules governing prior assessment for the purchase of medicines by National Health Service hospitals, whether for hospital use or for medicines subject to prescription, marketed only at hospital level. Decree-Law 48-A/2010 approved the general regime for state contributions to medicine prices, partially amended the rules of Decree-Law 195 of 2006 and modified the pricing regime for prescription medicines and

[40] Hauegen, Risk sharing agreements, op. cit., p. 99.

shared non-prescription medicines. In 2015, the Sistema Nacional de Avaliação de Tecnologias em Saúde (SiNATS) was created with Decree-Law 97, which reinforced the proposal that health technologies are subject to assessment and reassessment in an integrated context, with recourse to establishment through contracts with pharmaceutical companies that hold marketing authorizations.

Decree-Law 195, of 2006, determines that before using a medicine, it is necessary to reach an agreement with the manufacturer on the maximum price/annual budget, based on the estimated population that will use the product. If the budget is exceeded, the pharmaceutical company responsible for marketing will be obliged to refund the difference in price. The agreements were binding for two years, after which the values are reassessed, to determine whether to maintain or change the terms of the contract.

Decree-Law 97, of 2015, expressly provides that:

> 4—Contracts within the scope of health technologies may draw on co-participation or prior evaluation, which regulate, in particular, the following aspects, according to each type of contract and technology:
> […]
> e) Inclusion of the goals to be achieved after implementing the health technology, for purposes of reassessment;
> f) Indication of all the actions necessary for the creation and management of information that enables assessment of compliance with the targets established for use and effectiveness, in a real context, that is credible and scientifically based;
> g) Monitoring charging mechanisms, in terms of the contribution of the health technology the sustainability of the SNS;
> h) Clear and precise definition of the responsibilities of the various participants in implementing actions referred to in the previous paragraphs and the resources allocated;
> i) Setting of a limited period of time, after which the reimbursement is reduced, with an equivalent reduction in the sales price of health technology, or respective exclusion from reimbursement;
> j) Setting of a time period, during which additional evidence must be presented to support decisions to maintain the contribution or change the respective amount, in the case of reimbursement; or allow the acquisition of health technology by entities supervised by the Government health care official, in the case of prior assessment;

> k) Entities that can use health technologies subject to reimbursement or prior assessment;
> l) Establishment of restrictions on the use of health technology;
> m) Risk sharing mechanisms concerning the use of health technology;
> n) Duties or conditions considered appropriate to realize the purposes sought by the contract;
> o) Term, renewal, modification and termination of the contract.
> 5—Co-payment and prior assessment contracts must clearly reflect that the holder of the health technology assumes not only the risk inherent in possible failure to meet the targets set, but also the risk of the possible failure to obtain sufficient information regarding implementation of that technology and the consequent uncertainty as to the relative effectiveness asserted.
> 6—Participation and prior assessment contracts may be terminated at any time, in the event of non-compliance by one of the parties with the obligations set out therein. [emphasis added].[41]

Gonçalves et al.[42] note that the literature on the implementation of medicine risk-sharing contracts in Portugal is scarce; however, in a 2013 survey 84 agreements were identified, 74 of which were financial, two based on clinical results and eight mixed. There is no record of the results of these agreements, or their impact on the country's health system. There are records, however, of the types of medicines involved: two for oncological treatment, one for the treatment of rheumatoid arthritis, one for hepatitis C and one for periodic syndromes associated with cryopyrin (autoinflammatory diseases).

The authors also report that, in the specific case of hepatitis C, according to a report by Autoridade Nacional do Medicamento e Produtos de Saúde (Infarmed), the risk sharing contract generated positive results, "not only in terms of the clinical benefit for patients, but also the reduction in public expenditure with cost savings in treating the consequences of the disease evolution".[43]

The authors report that, accordingly, Portuguese public hospitals have been committed to developing information systems that facilitate the implementation

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41 PORTUGAL. Decreto-Lei nº 97/2015, de 1º de junho. Procede à criação do Sistema Nacional de Avaliação de Tecnologias de Saúde. Available at: https://diariodarepublica.pt/dr/detalhe/decreto-lei/97-2015-67356991. Accessed on: 4 June 2023.

42 Gonçalves et al., Risk-sharing agreements, present and future, op. cit.

43 Ibid., P. 8, loose translation.

of ACRs for medicines. This has also made doctors, especially oncologists, aware of the need to maintain records and add data to the clinical record—the electronic medical process—to enable monitoring of the use of medications and their results on patients.

3.4 The Brazilian risk sharing experience: the AME case

On April 24, 2019, Ministry of Health Ordinance No. 24, through Secretaria de Ciência, Tecnologia e Insumos Estratégicos, incorporated the medicine nusinersen, used to treat muscular atrophy (SMA) 5q type I, within the scope of the SUS, for patients with a confirmed genetic diagnosis not on permanent, invasive mechanical ventilation.

The ordinance also defined that patient care should be handled in centers of reference which provide multidisciplinary care, and assessment of clinical effectiveness, in accordance with the Clinical Protocol and Therapeutic Guidelines. The ordinance stated that Comissão Nacional de Incorporação de Tecnologias (Conitec) should reassess the arrangement within three years, from the date on which the ordinance was established.

On June 11, 2019, Ministry of Health Ordinance No. 1,297 sanctioned an ACR pilot project to incorporate health technologies, to offer access to the medicine Spinraza, for the treatment of SMA, which uses the active ingredient nusinersen. The agreement was created within the scope of the SUS, for AME types I and III.

The ordinance defined the arrangement between the Ministry of Health and the pharmaceutical company as a risk-sharing agreement incorporating health technologies, due to uncertainties concerning (i) the cost and effectiveness of the medicine incorporated into the SUS under real-life conditions and (ii) estimated consumption, considering the number of pills/doses and the budgetary impact.

The objectives of the pilot project were defined in order to: (i) enable, through ACR, incorporation of the drug Spinraza for the treatment of SMA 5q within the scope of the SUS; (ii) promote balanced medication costs for the SUS; (iii) collect additional evidence about the use of the medicine in real world conditions; (iv) enable reassessment of the incorporation of technology in light of additional evidence; (v) support publication of a future general standard for the ACR for incorporation of health technologies within the scope of the SUS; and (vi) promote research on AME 5q types II and III to guide public policy within the scope of the SUS.

The ordinance established that the ACR, as agreed with the pharmaceutical industry, should include: (i) a reduction in the price of the medicine; (ii) description of the disease and eligibility criteria for subgroups of patients benefiting from the ACR; (iii) definition of expected health outcome criteria and clinical effectiveness parameters; (iv) the maximum number of patients per year who will receive the technology funded by the Ministry of Health, based on epidemiological criteria and/or demand estimates, with the expectation that, once this number is exceeded, the pharmaceutical company will bear the cost of the medication for other patients; (v) definition of the criteria for interrupting the supply of the medicine for patients who do not present the expected health outcomes, within the defined time period a priori, according to the best scientific evidence available; and (vi) definition of the frequency of evaluation of clinical effectiveness parameters, in accordance with the best available scientific evidence.

Ordinance No. 1,297, 2019, established that the definition of the terms and conditions of risk sharing should arise from a statement from Secretaria de Ciência, Tecnologia, Inovação e Insumos Estratégicos em Saúde (SCTIE/MS), with the presentation of a technical basis for the criteria. It would also be up to SCTIE/MS to define the research institute which would monitor patients and carry out the assessment of clinical outcomes in recognized centers of reference. The same secretariat would carry out periodic evaluations of the pilot project to create general standard on risk sharing for the incorporation of health technologies within the scope of SUS.

Despite efforts to create the legal and administrative framework, the result was not encouraging. Caetano et al. note:

> Another innovation, this time associated with the purchasing process, is the so-called risk sharing agreement. This type of agreement aims to overcome the high degree of uncertainty about the effectiveness of treatments and their costs, to minimize the impact of the opportunity cost of decisions on incorporation. Linking the final price to future assessment is suggested as a mechanism to adjust the relationship between price and clinical value. In the contract, potential reductions in the ceiling price of the medicine are set, linked to certain outcomes, measured after the conclusion of the agreement, in real-life conditions. More developed countries (Spain, Canada, Australia, France, Sweden, England) have used different types of incorporation and acquisition.

> Specifically in relation to risk sharing, the price clause is subject to a future and uncertain event; this risk, an element that distinguishes the contract from traditional purchasing models, previously borne entirely by the purchaser, is now shared with the technology supplier. Although promising, it is considered difficult to execute given the high transaction costs and necessary structure for assessing health technologies and data collection, among other elements.
>
> In the process of incorporating nusinersena into SUS, some aspects suggest no sharing of risk. The possibility of donating the medicine is propitious for this type of contract, as it is a way of operationalizing price flexibility. Another way would be setting conditions for incorporation, such as center monitoring, mandatory data collection and subsequent reassessment based on real-world data.
>
> On the other hand, the final incorporation report no longer mentions provision of the medicine free of charge. Nor do the incorporation ordinance and the recommendation report establish any outcome linked to price fixing. There is no information on absolute or percentage price reductions concerning a possible future event. Significant uncertainty is not included as a contract item. At the time of writing this study, no regulations have been issued that established criteria and contractual rules for this type of acquisition.[44]

The experiment did not materialize and, consequently, did not produce results that might verify its use. However, the prospect of using risk-sharing contracts for high-cost medicines in Brazil, despite the difficulties highlighted by researchers, is gaining more weight and credibility.

4 Analysis of the Brazilian risk sharing law project

In March 2021, deputy Eduardo da Fonte presented Bill No. 667, not voted on, as it is awaiting the opinion of the Comissão de Seguridade Social e Família.

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[44] CAETANO, Rosângela; HAUEGEN, Renata Curi; OSORIO-DE-CASTRO, Claudia Garcia Serpa. A incorporação do nusinersena no Sistema Único de Saúde: uma reflexão crítica sobre a institucionalização da avaliação de tecnologias em saúde no Brasil. Cadernos de Saúde Pública, v. 35, n. 8, e00099619, 2019. Available at: https://doi.org/10.1590/0102-311X00099619. Accessed on: 5 Nov. 2022. https://doi.org/10.1590/0102-311X00099619.

The objective is to amend Law No. 8,080, of 1990, to create a Risk Sharing Agreement for the Incorporation of New Health Technologies into the SUS.

The bill defines an ACR for incorporation of health technologies, as well as the creation and sharing of a clinical protocol or guideline, between the Ministry of Health and the pharmaceutical company supplying it, due to uncertainties concerning (i) the cost and/or effectiveness of the drug or treatment incorporated into the SUS under real conditions and (ii) the estimated consumption, considering the quantity of medicine/doses and the budgetary impact.

The project establishes the following fundamental objectives for the ACR: (i) enable, through ACR, incorporation of a medicine or treatment within the scope of SUS; (ii) promote the balance of medication costs for the SUS and the rational use of the public budget; (iii) collect additional evidence on the use of the medicine in real conditions; (iv) enable reassessment of the incorporation of technology in light of additional evidence; (v) ensure transparency through access to detailed information on the elapsed time of use, effectiveness and dosage of the medication or treatment incorporated through the sharing agreement; and (vi) encourage research on medication or treatment, and guide public health policy within the scope of SUS.

The bill determines minimum elements that must be present in all risk-sharing contracts with the pharmaceutical industry: (i) reduction in the price of the medicine; (ii) the deadline for its completion; (iii) the proven benefit, at what levels; (iv) description of the disease and eligibility criteria for subgroups of patients benefiting from the ACR; (v) definition of expected health outcome criteria and clinical effectiveness parameters; (vi) the maximum number of patients per year who will receive the technology funded by the Ministry of Health, based on epidemiological criteria and/or demand estimates, with the expectation that, once this number is exceeded, the pharmaceutical company will bear the cost of the medication for other patients; (vii) definition of criteria for interrupting the supply of the medicine for patients who do not present the expected health outcomes within the defined time period a priori, according to the best scientific evidence available; (viii) definition of the frequency of evaluation of clinical effectiveness parameters, in accordance with the best available scientific evidence; (ix) participation of civil society entities in the final decision on the termination or extension of the ACR.

The project also foresees monitoring of patients and evaluation of clinical outcomes in reference centers, coordinated by a research institution recommended by SCTIE/MS, observing the agreements signed between the Ministry of Health

and the pharmaceutical industry. The secretariat would monitor and supervise the activities of the research institute.

To support the project, the author refers to Ordinance No. 1,297, 2019, and the fact that on February 4, 2021, in the minutes of the 94th Conitec meeting, the final opinion favored non-incorporation of the Spinraza medication.

In fact, at this meeting and in a report made available by Conitec, the conclusion was that "the majority of members agreed that the treatment was beneficial, but there were still uncertainties about the magnitude and sustainability of this in the long term".[45]

Consequently, the final recommendation was not to use nusinersen for the treatment of SMA 5q types II and III (late onset).

Analysis of this specific case reveals a typical situation in which risk sharing would have been beneficial: a high-cost medicine with weak evidence as to its effectiveness, especially for specific situations such as those highlighted in the report.

Natássia Misae Ueno explains:

> It is through scientific evidence—largely clinical trials—from the pharmaceutical industry, for registration of medicine with Anvisa, that the quality, efficacy and safety of the product are determined, which is thus fundamental to support incorporation of the medicine by SUS. However, clinical trials are carried out in experimental settings and thus differ from actual practice.
> […]
> Part of the health technology assessment process is analysis of clinical evidence on the safety and efficacy of the medicine. Such evidence, however, is only confirmed when the medicine is used in real life situations, outside clinically controlled research. Analysis of the cost-effectiveness and therapeutic value of the product will gain full weight once the medicine enters the health care system.[46]

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[45] BRASIL. Ministério da Saúde. Conitec. Relatório de recomendação n. 595: nusinersena para tratamento da atrofia muscular espinhal 5q tipo II e III (início tardio). Brasília, DF, Feb. 2021. Available at: https://www.gov.br/conitec/pt-br/midias/audiencias_publicas/relatoriorecomendacaoconitec_nusinersena_ameiieiii.pdf. Accessed on: 3 Nov. 2022.

[46] UENO, Natássia Misae. Acordos de risk sharing para aquisição de medicamentos pelo governo no abastecimento do SUS: análise jurídica à luz do caso do nusinersena. Dissertação (mestrado em direito)—Escola de Direito de São Paulo, Fundação Getulio Vargas, São Paulo, 2020.

In the industrial production of medicines, companies invest large amounts in research, which often does not achieve the expected results, leading to considerable losses. After the clinical research stages, the medicine is freely available for use on the market, without the monitoring conditions of the previous phases or the option of deciding on who will use the medicine. At this stage, its effectiveness will be truly tested, in, to all intents and purposes, a fifth phase of clinical trials, with data gathered from real-life use, far from the laboratory setting.

Bruno Henrique Silva Santos states:

> It is necessary to distinguish the efficiency of a health technology from effectiveness, as both are required for incorporation into the Unified Health System. Efficiency concerns the results obtained with the use of technology under ideal research conditions and in a controlled environment, and through laboratory analyzes or clinical case studies monitored by competent professionals, through prior and careful selection of patients. Effectiveness relates to the results of a technology in real conditions of use by patients, outside a controlled environment, susceptible to the variable complications which can be avoided by constant monitoring by scientists.[47]

Cf. Hauegen:

> […] the final beneficiary of a new medicine will not be the same as the ones included in a trial. Thus, there is uncertainty as to the extent to which the benefits will be the same. This raises the matter of demonstrating the efficacy of a new drug among subgroups, which may require much larger trials involving differential efficacy.
> Trevor Jones, former president of the Association of the English Pharmaceutical Industry (ABPI), recognized the fragility of clinical trials, as patients are carefully chosen for clinical trials, with many exclusion elements. For him, the true worth of the treatment will only be known years hence.[48]

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47 Santos, Acordos de compartilhamento de riscos para incorporação de tecnologias em saúde pelo SUS, op. cit., p. 72.

48 Hauegen, Risk sharing agreements, op. cit., P. 5.

ACRs based on performance mean the product can be offered patients, as practical evidence becomes more robust. The pharmaceutical industry will share real risks that will only become known when it is applied in the real world, when the people who use it are not previously chosen, and there is no monitoring of the regularity of use or side effects.

The initial phase of drug consumption on the market is one of uncertainty and, strictly speaking, constitutes a final stage of clinical testing, a moment when doctors, patients and the pharmaceutical industry itself will discover practical results, consequences and, mainly, whether the intended outcomes were achieved and over what period.

If it is true no pharmaceutical product released onto the market can respond to all the uncertainties surrounding its use, it is no less correct that risk sharing fulfills an important task: allowing the situation to be balanced for the cost provider—public or private—and for the medicine producer.

In cases of serious or rare diseases, of low frequency but with extensive results data, shared risks are even more appropriate during the first phase of use on the market. At this stage the laboratory will better understand the situation and be able to readjust the composition and prescription, to correct errors. New applications may even be detected for the medicines, as has happened many times.

Whether the results are positive or negative, the pharmaceutical industry can learn a lot from the first phase of everyday practical use, which is fundamental for continued research, to identify new benefits and, as stated, correct errors, especially possible side effects.

Risk sharing balances the relationship between the buyer and the pharmaceutical industry, provides safer use for the patient, reassures doctors when prescribing the medicine and, above all, makes the product more accessible to all.

5 Relevance of sharing in view of the recently approved law for the ANS list of health procedures and events

On September 21, 2022, Law No. 14,454 was enacted, amending Law No. 9,656, 1998. The soo-called Health Plan Law ruled that, in the case of treatment prescribed by an assistant doctor or dentist which is not included on the list of health procedures of Agência Nacional de Saúde Suplementar (ANS), coverage

must be authorized by the health plan operator, as long as (i) there is proof of effectiveness, based on scientific evidence and a therapeutic plan, or (ii) there are recommendations by Conitec in the SUS, or there is a recommendation from, at least, a renowned international health technology assessment body approved in Brazil.

The rush to pass the law that mitigated the ANS list taxability may have led to omission of the pharmaceutical industry from the dialog, with adoption of criteria for risk sharing in cases where medication is expensive with respect to rare or serious diseases.

The bill would have benefited from including preliminary aspects, of a practical nature, to enable consolidation of criteria for the adoption of medicine risk sharing for such diseases.

If the practical experience of different countries, detailed in numerous scientific articles in the last 10 years, demonstrates concrete difficulties with risk sharing, especially regarding specification of the relevant data required to measure the effectiveness and, consequently, price fixing, then, it is fair to say there are, currently, affordable technologies available to overcome these obstacles.

Some medications require a longer time for their effectiveness to be assessed, which is certainly a negative factor for building risk sharing. Other medicines are quickly replaced by more effective ones, arising from research carried out using real-world data, which may also be an impediment to risk sharing. Other factors may also be considered impediments or, at least, hindrances.

Several certainties, however, must be considered, which could have been included in the law, to facilitate drafting of risk-sharing contracts. Among others, the following may be mentioned: (i) medication for rare and serious diseases is high-cost; (ii) risk sharing balances the relationship between the payer and the pharmaceutical industry, always desirable in free markets; (iii) one of the fundamental roles of the ANS is to mitigate market failure, which clearly happens when an entity maximizes its profits based on real-life use, paid for by another economic entity (health operators), who do not benefit from the use of this same data; and (iv) risk sharing makes pharmaceutical products more accessible to consumers, which the ANS must ensure.

The existence of a bill on SUS risk sharing rules could, potentially, have stimulated debate on the topic, aimed at adoption of such criteria in the law approved for the supplementary health sector. However, as highlighted, the high cost of medicines demands greater discussion and configuration of risk models, suggesting a moral debate on the acquisition of medicines and the inclusion of new technologies.

6. The moral dimension

Consideration of health, and thus health care, as a fundamental right naturally provokes discussion: on financing, evaluation metrics and the ethical limits of treatments and medications.

Arising from ethical propositions and anchored in the constitutional guarantee of health for all, the debate on technology and its application in health care entails important decisions, reconciling public interests and cost efficiiency. According to the Conitec report, a "continuous process of analysis and synthesis of the health benefits, and economic and social consequences of health technologies",[49] ATSs are at the juncture of the "right to hope" and responsible expansion of the welfare state.

Table 1
Right to life or hope?

On the right to hope
Discussion of the right to hope is linked to the doctoral thesis by researcher Cynthia Pereira de Araújo, entitled Is there a right to hope? Health in the context of cancer and end of life care, defended in 2018 at the Pontifical Catholic University of Minas Gerais (Postgraduate Program in Law). In an in-depth treatment of the judicialization of health as justified by the right to life, often expressed in the right, not effectively to extension of life, but to the granting of hope, the author highlights an important debate on the balanace between individual desires and health provision in collective terms. She describes the right to hope as follows: > The idea of a right to hope, as far as we know, has never been developed. In 2014, a Google search for the expressions "direito à esperança", "right to hope" and "Recht auf Hoffnung" returned no results. However, Groopman entitles one of the chapters of the work

[49] BRASIL. Ministério da Saúde. Secretaria de Ciência, Tecnologia, Inovação e Insumos Estratégicos em Saúde. Departamento de Gestão e Incorporação de Tecnologias e Inovação em Saúde. O uso de limiares de custo-efetividade nas decisões em saúde: proposta para as incorporações de tecnologias no Sistema Único de Saúde. Brasília, DF, 2021. Available at: https://www.gov.br/conitec/pt-br/midias/artigos_publicacoes/20211202_relatorio_oficina_limiares.pdf. Accessed on: 28 Sept. 2022.

> The Autonomy of Hope—at that time not known to the author—as "Right to hope", without theorizing further. Marcel, as will be seen, also speaks of the "right to hope". Note that, when participating in the public hearing called by then President of the Federal Supreme Court (STF), Minister Gilmar Mendes, in 2009, for instruction of Agravos Regimentais nas Suspensões de Liminares nºs 47 e 64, Suspensões de Tutela Antecipada nºs 36, 185, 211 e 278, and Suspensões de Segurança nºs 2361, 2944, 3345 e 3355 doctor Paulo Hoff used the expression "Medicine based on hope"—not medicine based on evidence—to refer to situations in which… "when you have a patient sitting in front of you, with terminal cancer, who wants to make a choice, and sometimes, the doctor feels compelled to use a medication that is not always sufficiently proven. This practice should not be encouraged, but we must recognize that this factor exists."[50]

Source: prepared by the authors in Araújo, Existe direito à esperança? op. cit., P. 31.

The idea of a right to hope thus presents a dilemma and paradox: if a new technology, a new medicine with the potential to cure a condition (cancer, in the author's study) and extending life is available, the existence of hope may prove useless or even harmful, where the treatment is ineffective or administered inefficiently. In this sense, the result may not be material improvement, but rather an emotional, physical and financial cost that sets back debate and research.

The synergy between ethical limits in health care and dissemination of technologies (treatments and medicines) points to application criteria focused on efficiency, efficacy and effectiveness, not ignoring the constitutional precept of the right to enjoy good health. The decision, then, can, and perhaps should, be based on a singular factor: risk.

A model that addresses risk is, therefore, vital to researchers, administrators, society at large and all those interested in making health provision accessible, notwithstanding potential misuse and the possibility of varied risks. Among the proposals are the risk sharing model, whereby healthcare providers spread the risks associated with a new medicine or delivery of a healthcare technology to the general population. In 2019, as determined by the federal government,

[50] ARAÚJO, Cynthia Pereira de. Existe direito à esperança? Saúde no contexto do câncer e fim de vida. Tese (doutorado em direito)—Pontifícia Universidade Católica de Minas Gerais, Belo Horizonte, 2018. p. 31. Available at: http://www.biblioteca.pucminas.br/teses/Direito_AraujoCP_2.pdf. Accessed on: 28 Sept. 2022.

entities linked to public administration were instructed to reassess the regulatory framework, including the rule that regulates risk sharing operations. Normative Resolution No. 517 came into force in 2022, providing for the management of risk sharing involving health care plan operators.

Table 2
Risk Sharing Definitions

Risk sharing: ANS definition
Risk sharing deals with mechanisms for sharing risk management by health plan operators, creating protective rules for health plan contractors and providers. Normative Resolution No. 517/2022 regulated three main models: 1. Co-responsibility for the management of risks arising from the continuous care of beneficiaries of other operators through exchange, reciprocity arrangements or other agreements. 2. Creation of a common fund to minimize, in the short term, the financial impact of health care, and the sharing of management service costs, such as the audit of medical bills, may be associated with this fund. 3. Joint offer of private health care plans. Operators can mitigate the financial risks associated with their activities by taking out insurance or reinsurance, subject to the restrictions and rules set out in the applicable legislation in the insurance sector. It is also important to highlight that mutual collaboration aimed at sharing the management of risks associated with private health care plans cannot imply the transfer of any responsibility from one operator to another regarding the beneficiaries and the ANS.

Source: BRASIL. Ministério da Saúde. Agência Nacional de Saúde Suplementar. Compartilhamento de riscos. 5 maio 2021. Available at: https://www.gov.br/ans/pt-br/assuntos/operadoras/regulacao-prudencial-acompramento-assistencial-e-economico-financeiro/regulacao-prudencial-1/share-de-riscos. Accessed on: 28 Sept. 2022.

A risk-sharing model is not a panacea that will resolve the proposed dilemma of the right to hope or make diffusion of health technologies entirely efficient. But undoubtedly, it is an instrument that, besides providing greater transparency for health service contractors (including the contracting of health plans, use of medicines, etc.), provides legal, regulatory certainty.

For the risk sharing model to be a strategy for increasing effectiveness, efficacy and effectiveness, it is necessary to identify and create, if necessary, assessment measures. To define evaluation criteria, one of the proposals is for the establishment of a cost-effectiveness threshold.

7 Cost-effectiveness threshold proposal

Health Technology Assessment (HTA) can be defined as a "Multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its life cycle. The goal is to inform decision-making, to promote an equitable, efficient, and high-quality healthcare system."[51]

The initiative is a product of a joint working group led by the International Network of Agencies for Health Technology Assessment (Inahta) and the International Society for Health Technology Assessment (HTAi), focused on assessment of whether a technology should or not be used in the provision of healthcare.

The creation of a risk sharing criterion involves, firstly, its definition. In Table 2, based on the definitions in the ANS memorandum, three forms of sharing risk management were described. A common demand from the parties involved, definition of risk sharing gives rise to the methodological unfolding of this model. Discussions around the topic generate the need for an effective and, above all, metricable and comparable criterion. In this scope, discussion around the cost-effectiveness threshold has gained strength and is advanced here a positive development.

[51] BRASIL. Ministério da Saúde. Secretaria Executiva. Área de Economia da Saúde e Desenvolvimento. Avaliação de tecnologias em saúde: ferramentas para a gestão do SUS. Brasília, DF: Editora do Ministério da Saúde, 2009. (Série A. Normas e Manuais Técnicos). p. 27. Available at: https://bvsms.saude.gov.br/bvs/publicacoes/avalicao_tecnologias_saude_ferramentas_gestao.pdf. Accessed on: 4 June 2023.

Table 3
Cost-effectiveness threshold

Cost-effectiveness threshold: a definition
According to Soarez and Novaes, > The concept of cost-effectiveness "threshold" was originally proposed in 1973 by health economists. It is represented as a ratio between a monetary cost, generally expressed in national currencies, for example, the real (R$) as the numerator and a measure of health gain in the denominator. This value should be compared to the results of economic evaluation studies (incremental cost-effectiveness ratio—ICER) to guide decisions on incorporating technologies into health systems. If an ICER is below the threshold, the intervention should be incorporated.[52] In parallel, Rede Brasileira de Avaliação de Tecnologias em Saúde (Rebrats) highlights, in light of the Public Consultation which evaluates the proposal for the use of cost-effectiveness thresholds, that: > Recommendations for the threshold suggest that cost-effectiveness should not be an isolated parameter in health decision-making and that it is important to consider QALY (life gains) as the main outcome. 1 GDP per capita was established as the reference for cost-effectiveness, with possible adoption of alternative thresholds to promote innovation and equity in exceptional cases, among other aspects.[53]

Source: prepared by the authors based on Rede Brasileira de Avaliação de Tecnologias em Saúde (Rebrats), Consulta pública que avalia proposta de uso de limiares de custo-efetividade nas decisões em saúde tem prazo prorrogado, op. cit.

[52] SOAREZ, Patricia Coelho de; NOVAES, Hillegonda Maria Dutih. Liminares de custo-efetividade e o Sistema Único de Saúde. Cadernos de Saúde Pública, v. 33, n. 4, abr. 2017. Available at: http://cadernos.ensp.fiocruz.br/csp/artigo/75/limiares-de-custo-efetividade-eo-sistema-unico-de-saude#C8. Accessed on: 28 Sept. 2022.

[53] REDE BRASILEIRA DE AVALIAÇÃO DE TECNOLOGIAS EM SAÚDE (REBRATS). Consulta pública que avalia proposta de uso de limiares de custo-efetividade nas decisões em saúde tem prazo prorrogado. 24 June. 2022. Available at: https://rebrats.saude.gov.br/banners/787-consulta-publica-avalia-proposta-de-uso-de-limiares-de-custo-efetividade-nas-decisoes-em-saude. Accessed on: 28 Sept. 2023.

As discussed in the introduction, application of new technologies and the necessary assessment require delimitation and an adequate methodology to prevent present costs becoming future risks. Thus, use of a cost-effective threshold is included in the current proposals, including an open public hearing at Conitec. Its explicitness, not without criticism, would give rise to a comparable reference in which, based on establishment of these measures, progress could be made in terms of the natural heterogeneities of any health related service. The main factor is the acquisition of and access to health technologies (HS), based on (i) demand (preferences and, therefore, willingness to pay), (ii) supply (opportunity cost, effect of the most beneficial alternative to be financed if the intervention were implemented) or (iii) both.

In international doctrine, adoption of a cost-effective limit has been deliberated for some time. The idea is to identify, from a demand perspective, how much each person would be willing to pay for an additional year of healthy life.

> The most cited cost-effectiveness threshold for many years, is that published by the WHO Macroeconomics and Health Commission in 2001. Based on the GDP per capita of the country and estimating the economic cost of a year of healthy life, the threshold suggests that interventions that avoid a DALY of less than 1 GDP per capita of the country are considered very cost-effective; interventions up to 3 GDP per capita are still considered cost-effective; those above this value not.[54]

7.1 Criticism, application and advances

The discussion at Conitec and consequent opening of public consultation are important steps towards potential adoption of a cost-effectiveness threshold in Brazil. Three studies, in particular, form part of a survey carried out as to possible threshold limits in the country:

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[54] Soarez e Novaes, Liminares de custo-efetividade e o Sistema Único de Saúde, op. cit.

Table 1
Threshold limits: doctrine

Institution	Limits
Comissão Nacional de Incorporação de Tecnologias no SUS (Conitec)	1. Maximum value of BRL 81.675/DALY (3 GDP per capita/Daly).[55] 2. Threshold range between BRL 1,361 and BRL 147,016.00. 3. Three threshold levels: 4. Low (< BRL 25,000); 5. Average (BRL 25,000 to BRL 70,000); 6. High (> BRL 70,000).
University of York	$PPP 3,210—$PPP 10,122
Instituto de Efectividad Clínica y Sanitaria (Argentina)	$PPP 8,885—$PPP 11,401/QALY

Source: Prepared by the authors.

Some criticisms of the applicability of thresholds deal with the disclosure of limits, but also with the choice of variables that make up these limits. If, on the one hand, explicit adoption provides greater transparency, the manipulation of indicators, further impacting resource efficiency, may be possible. In addition, the choice of gross domestic product (GDP) per capita as the threshold (compared to Daly), although indicative of the country's wealth, does not express issues that are essential for the absorption of technologies, such as income inequality, regional disparities, as well as personal and social preferences. In this sense, part of this text contributes to the adoption of a model that converges on the establishment of a limit which absorbs these criticisms.

The proposal of this group, then, is to create an expansion of limits based on (i) income per capita and (ii) in income per capita per unit of the Federation.

[55] GDP per capita for each disability-adjusted life year.

8. Conclusion

Risk sharing can have a positive indirect result, engaging a greater number of stakeholders in dialogue prior to decision making. Many different voices may be heard, from Government and industry, healthcare providers and the pharmaceutical industry, to medical specialists, teaching and research institutions, universities, patient associations, and consumer protection organizations, broadening the debate and the responsibility for results.

Health is s fundamental right and State duty. In Brazil, the State has ceded part of its responsibility to the private sector, but adequate health provision remains foundational. Thus, risk sharing between supplementary healthcare and the pharmaceutical industry is not merely a matter of a private agreement. Primarily, it is the search for mechanisms that enable the realization of public interest drawing on the private health system. The objective is the same: access to instruments that provide quality health for all, with risk sharing involving private operators for realization to accomodate the highest level of public interest.

There is no doubt that any proposal that, directly or indirectly, purports to guarantees access to treatment, technologies and medical care will provoke stimulate moral discussion. The unequivocal search to ensure the fundamental right to health must be all encompassing, maintained through generations and anchored in the results and constitutional imperatives that outline social policy: effectiveness, efficacy and efficiency. Health guarantees need to be sustainable and effective over time, and, to this end, the health care model of risk sharing can simultaneously support investment and production incentives and a population with greater access to medicines.

Discussion is growing among theorists, interested bodies and society as to the most viable, appropriate risk sharing models for Brazilian health service provision. Among the proposals, adoption of a cost-effectiveness threshold is at an advanced stage of debate, in conjunction with Conitec, and must be closely monitored, with broad academic and social involvement.

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