The experts' point of view

Life Sciences

Range of partnership opportunities in the health sector opens up in 2024 with billion-dollar investments

For the second half of 2024, experts expect new business models and partnerships to emerge from the Health PAC, as well as companies seeking synergies through major acquisitions in the sector

Exclusive interview with our partners on the panorama of the sector

Business Barometer: opportunities and points of attention in the market

Lefosse

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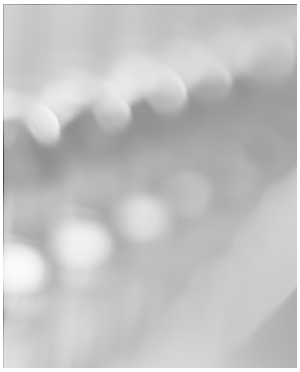

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COVER STORY

A range of partnership opportunities in the health sector opens up in 2024 with billionaire investments.

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BUSINESS BAROMETER

Stay ahead in the market: check out the opportunities and points of attention in the Life Sciences business.

The main prospects for the Life Sciences sector in Brazil for those who want to stay ahead in the market.

The review from **The experts' point of view: Life Sciences** offers a complete overview of the sector, with analysis and insights from our experts on the regulatory, transactional, tax and litigation fronts.

In the **cover story**, partners **Rubens Granja** and **Maira Materagia Imperatriz**, from the Life Sciences & Healthcare practice, **Ana Carolina Utimati**, from the Tax practice and **Laura Affonso**, from the Corporate and M&A practice, analyze the opportunities for partnerships in the health sector in 2024, based on the new business models and partnerships emerging from the Health PAC, as well as companies seeking synergies through major acquisitions in the sector.

In a **full interview with our experts**, we present the current scenario in the sector, outlining the business landscape, the highlights of the regulatory agenda and the potential loopholes for disputes in the sector. The partners also comment on important issues for the sector, such as the main innovations and effects of Law 14.874/2024 on the scenario of clinical research with human subjects, as well as the impacts of RDC 786/2023 on the market, with the permission to carry out certain types of laboratory tests in pharmacies.

Finally, our partners are looking forward to the judgment on the constitutionality of Law 14.454/2022, which establishes criteria for covering exams or treatments outside the ANS list of mandatory procedures.

In the **business barometer**, you'll find the main opportunities and points of attention in the Life Sciences sector so you can prepare for what is to come.

Happy reading.

Range of partnership opportunities in the health sector opens up in 2024 with billion-dollar investments

For the second half of 2024, experts expect new business models and partnerships to emerge from the Health PAC, as well as companies seeking synergies through major acquisitions in the sector

After a boom in demand during the Covid-19 pandemic and major mergers and acquisitions, the healthcare sector is facing opportunities for partnerships and the development of innovative business models, say the partners of Lefosse's Life Sciences & Healthcare practice.

Rubens Granja highlights the potential attraction of investments to carry out clinical research with human subjects in Brazil as a result of the improvement in the regulatory scenario with the recently approved Law 14.874/2024. He also draws attention to the new businesses and partnerships that are expected to emerge from the so-called Health PAC, which expects investments of R$ 42 billion by 2026 in the implementation of the National Strategy for the Development of the Health Economic-Industrial Complex.

These are public funds, Granja explains, that should be allocated to infrastructure - such as the construction of a high-security laboratory - and to the health services and products sector.
“The expectation is that the contracts will actually begin to be signed at the end of the year, in order to take advantage of the 2024 budget. They should come off the drawing board because there's a budget earmarked for it”, he says.

The expectation is that contracts for new business and partnerships in the sector will actually begin to be signed at the end of the year, in order to take advantage of the 2024 budget."

Rubens Granja

In the supplementary health segment, Maira Materagia Imperatriz observes that there are windows for operators, hospitals and laboratories to think about innovation, moving away from the traditional fee-for-service model, in which remuneration is made per service provided without taking into account other factors such as performance, predictability and clinical outcome.

"In 2024, more strategic investments are expected in new business models, with innovative solutions, including the use of new technologies, for example", he says, stressing that, in parallel, there is a task force from the National Supplementary Health Agency (ANS) to evolve the economic and financial requirements of operators in an attempt to retain companies in the sector.

In 2024, more strategic investments in new business models are expected, with innovative solutions, including the use of new technologies, for example."

Maira Materagia Imperatriz

For Laura Affonso, a partner in the Corporate and M&A practice, after major consolidations in the last two years - such as with Hapvida and Notre-Dame, SulAmérica with Rede D'Or, Fleury and Hermes Pardini - companies in the health sector are thinking about how to capture synergies from these major mergers and acquisitions. "We see negotiations starting and structures being thought out, but they're not closed yet. I think that this will tend to happen more in the second half of the year", she says.

Partnerships and M&As may arise, say the partners, from a new rule from the National Health Surveillance Agency (Anvisa) that allowed some types of clinical analysis tests to be carried out in pharmacies (RDC 786/2023). "Pharmacy chains are committed to implementing the new standard and we have already seen a significant increase in the range of their services. Laboratories have also been moving on the subject, structuring how this can work in different environments", says Maira. For Granja, the next leap in this area could be through partnerships between laboratories and drugstores. "I've seen this movement in conversations with clients at both ends. There is synergy", he says.

As points of attention for the sector, the partners highlight the sensitive issue of drug pricing and the uncertainty over the list of treatments, exams and surgeries that must be covered by health plans.

With regard to the price of advanced therapies, Granja points out that there is no prospect of a decisive decision to settle the issue. "The long-term trend is for the government to negotiate bilaterally with companies that put new products on the market, anticipating legal disputes", he says.

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Rubens Granja

For 2024, there is an expectation of a judgment on the constitutionality of Law 14.454/2022, which set criteria for covering exams or treatments outside the ANS list of mandatory procedures. According to Maira, another way out of the imbroglio could come with the publication of a decree regulating the conditions for granting this coverage.

From a tax point of view, the health sector is still dealing with uncertainties related to the new tax payment model provided for in the tax reform (Constitutional Amendment 132/2023), which has yet to be regulated. But according to Ana Carolina Utimati, a partner in the Tax practice, there is another urgent issue for pharmaceutical companies is something.

Taxpayers have questioned the new Law 14.789/2023, which changed federal taxation on ICMS incentives. The rule changed the way in which investment grants are excluded from the basis for calculating Corporate Income Tax (IRPJ) and Social Contribution on Net Profits (CSLL). "This discussion has gone ahead of the tax reform, because it's really what's been having an effect on companies since January. It's the most urgent issue with a strong impact on the pharmaceutical industry", she says.

INTERVIEW

What do **our experts** have to say about the main **innovations in the sector?**

In the interview below, partners **Rubens Granja** and **Maira Materagia Imperatriz**, from the Life Sciences & Healthcare practice, **Ana Carolina Utimati**, from the Tax practice and **Laura Affonso**, from the Corporate and M&A practice, share their analysis of the current scenario in the sector. They outline the business landscape, the highlights of the regulatory agenda and identify potential loopholes for disputes in the sector.

In addition, they discuss the main innovations and effects of Law 14.874/2024 on the scenario of clinical research with human subjects, as well as the impacts of RDC 786/2023 on the market, with the permission to carry out certain types of clinical analysis tests in pharmacies. Finally, they comment on the expectation for the judgment on the constitutionality of Law 14.454/2022, which establishes criteria for covering exams or treatments outside the ANS list of mandatory procedures.

QUICK MENU

Quickly access topics of interest:

- OPPORTUNITIES FOR THE HEALTH SECTOR IN THE COMING YEARS
- HEALTH PAC UPDATES
- OPPORTUNITIES IN THE SECTOR
- PROSPECTS FOR NEW INVESTMENTS AND M&AS
- MAIN INNOVATIONS AND EFFECTS OF LAW 14.874/2024 ON CLINICAL RESEARCH WITH HUMAN SUBJECTS
- IMPACTS OF RDC 786/2023 ON THE MARKET: CLINICAL ANALYSIS TESTS IN PHARMACIES
- POINTS OF ATTENTION THAT CAN LEAD TO LITIGATION IN THE SECTOR
- SCENARIO ON THE ANS LIST OF PROCEDURES
- PRODUCT PRICING
- HIGHLIGHTS OF THE REGULATORY AGENDA FOR THE COMING YEARS

What opportunities do you see for the health sector in the coming years? How should the implementation of the National Strategy for the Development of the Health Economic-Industrial Complex affect the sector?

Rubens Granja: What the government has called the Health PAC could create many opportunities in the health sector, because it involves a significant amount of public investment. These are investments in the services sector and in health products. When we talk about strengthening the

health industrial complex in Brazil, the government is basically indicating investments in building infrastructure, acquiring psychologists and ambulances, building high-security laboratories, specially because of the experience of Covid-19.

What the government has called the Health PAC could create many opportunities in the health sector, because it involves a significant volume of public investment."

Rubens Granja

Even though we were willing and able to produce the vaccine here, we couldn't bring the active ingredient to Brazil, for example. We have always had to import because we do not have a laboratory with a high level of security. In fact, there are only a few in the world: in China, France and the United States.

The investments also involve the resumption of the Partnerships for Productive Development (PDPs) project. The partnerships were somewhat ostracized for a while, largely because of a questionably successful experiment. Some PDPs worked, but others did not. It is a very bold project, and the government has been talking about resuming it.

Our clients have been approached by the government to discuss their interest in transferring technology to Brazil, which basically means teaching Brazilian public laboratories - Fiocruz, Butantan, Tecpar - to produce products locally. The laboratories know that they have a short period of time to exploit the patents on these products and they begin to negotiate the transfer of technology to the national laboratories in advance. There is the possibility of paying royalties, but it is not usually done like this. These projects are paid for by the acquisition of the product, not least specially because some of the projects involve products with expired patents. This implies the incorporation of new products by SUS and the supply of more medicines to the population.

Our clients have been approached to discuss their interest in transferring technology to Brazil, i.e. teaching Brazilian public laboratories how to produce products locally."

Rubens Granja

It is a project that generates a series of opportunities. For a law firm, we see opportunities for financing teams, infrastructure teams, regulatory teams and teams focused on transactions, as it involves the formation of partnerships from a contractual point of view.

What is the current status of the Health PAC?

Granja: There was an initial movement during the launch, with the appointment of those responsible for running the initiative. This led to some public events with the participation of the Ministry of Health and the Ministry of Finance, to tell them how the investments would work. But now we are between the launch of the program and the actual start of investments, waiting for a clearer structure from the government.

There are some obstacles to restructuring the PDP model. The government has been discussing its strategic products. Then you have to assess what went wrong in the past and what needs to be rectified.

The initial promise was that the project would start to come off the drawing board in March. Now there is talk of a second semester. Perhaps the contracts will actually start to be signed towards the end of the year, to take advantage of the 2024 budget. Yes, it should come off the drawing board because the budget is earmarked for it.

Is it the project that should drive the market in the coming years or are there other fronts of opportunity?

Maira Materagia Imperatriz: In the area of supplementary health, there is an ANS task force to evolve the economic and financial requirements of operators in an attempt to retain these companies in the sector. It is publicly known that operators are facing major challenges in terms of the sustainability of their market. The simplification of regulatory rules on guarantee assets or even on the solvency of operators is something the sector has been waiting for a long time. This will allow for greater flexibility in the pricing of health plans, including readjustments, in an attempt to balance the sustainability of the sector, as well as access and permanence for beneficiaries.

Another opportunity for the coming years that I see for operators and for the health institutions themselves is to have a more integrated supplementary health sector, with the implementation of policies aimed at the interoperability of information between the public and private networks, initially through the national health data network and very intense discussions about the Open Health. I believe that, by 2024, there will be significant progress on the issue and we will have triggered a specific policy aimed at the sector.

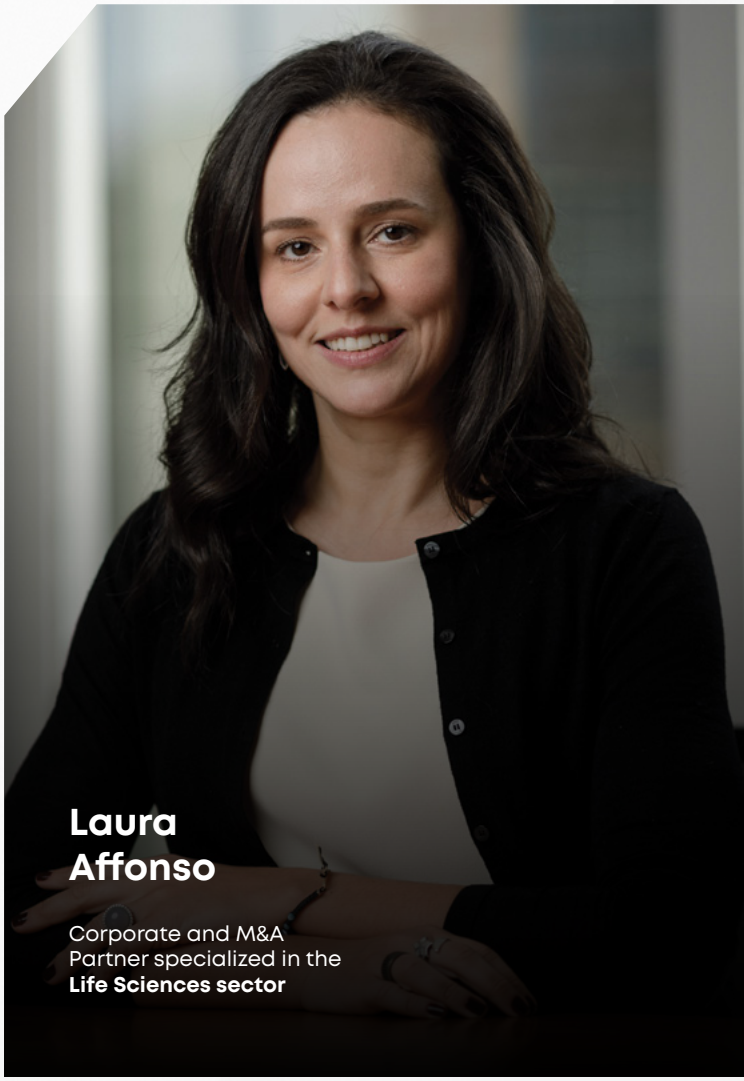
In the area of supplementary health, there is an ANS task force to evolve the economic and financial requirements of operators in an attempt to retain these companies in the sector."

Maira Materagia Imperatriz

Investments in new business models also bring opportunities. With the pandemic we have seen a very high number of operations targeting the sector. By 2024, more strategic investment is expected in new business models, with innovative solutions, including the use of new technologies, for example. We see a trend towards discontinuing the exclusive application of the traditional fee-for-service model, in which the operator pays for the quantity of services provided by the healthcare institution. This opens up an opportunity for greater inclusion of alternative remuneration models, such as bundles, capitation, performance-based remuneration and other forms of remuneration to guarantee innovation and sustainability in the sector.

For the next few years, companies are thinking about capturing synergies from large acquisitions."

Laura Affonso



Along these lines, how do you assess the scenario for new investments in the health sector? What are the prospects for mergers, acquisitions and corporate reorganizations?

Laura Affonso: There was a reduction in the volume of mergers and acquisitions in 2022 and 2023, including in the health sector. But at the same time, in Brazil, we have had major mergers and acquisitions in recent years, such as with Hapvida and Notre-Dame, SulAmérica with Rede D'Or and Fleury with Hermes Pardini. These were very important consolidations that changed the structure of the sector.

The house is now in order. For the next few years, the companies are thinking of capturing synergies from these major acquisitions. Therefore, big market movements are less likely now. But there is a trend towards verticalization. There are clinics, which are still centralized, where we see small acquisitions, in a more strategic way.

With regard to healthtechs, we see smaller operations, but with volume. From corporate venture capital interested in bringing it in-house, to more pure venture capital starting to come back and large investment funds that have raised specific funds for health thinking about how to invest.

In 2024, more strategic investment is expected in new business models, with innovative solutions, including the use of new technologies, for example."

Maira Materagia Imperatriz

We have seen the Brazilian market seeking to set up new research companies and to train professionals."

Rubens Granja

Falling interest rates and other macroeconomic elements signal potential investment, but we do not see this happening yet. We see negotiations starting and structures being thought out, but they are not closing yet. I think that this will tend to happen more in the second half of the year.

The debt area is getting faster, even for companies in the health sector. Partnerships are also being formed with universities through the corporate mechanism of joint ventures. We see international players wanting to enter Brazil to test the waters before making a bigger investment.

Granja: Partnerships have also been made with Brazilian hospitals. The area of clinical research has attracted a lot of attention. Brazil has shown itself to be an interesting place for clinical research during the pandemic and with the capacity for a lot of growth. We have seen, for example, foreigners seeking partnerships with large Brazilian hospitals. They are major research centers in Brazil, but they are still islands. We have seen the search for the Brazilian market, including for the creation of new research companies and for the qualification of professionals.

What are the main innovations of Law 14.874/2024, which provides new rules for clinical research with human subjects? What is the potential effect of the standard on the market?

Granja: It was a long-awaited legal milestone for anyone who wants to do research in Brazil. It was sanctioned after almost a decade of debate in Congress. The tendency is for partnerships to be motivated because the standard places the country in a new scenario and increases our potential to receive investment from new research projects.

Law 14.874 guarantees greater legal certainty for the agents involved and speeds up the approval of clinical trials in Brazil. Anvisa now has 90 days to analyze clinical research projects with human subjects for the purpose of registering the product under investigation. If the Agency does not give its opinion within this period, development can begin provided it has the appropriate ethical approvals.

The tendency is for partnerships to be motivated, since Law 14.874 places the country in a new scenario and increases our potential to receive investment from new research projects."

Rubens Granja

INTERVIEW

There was a significant veto on the issue of supplying the drug to the participant after the end of the study. The bill limited this free supply to five years from the drug's commercial availability. The veto will still be analyzed by the Legislative Branch. If it is maintained, the rule that the benefiting participant has the right to receive the medicine indefinitely will apply.

In order to effectively apply the law, Anvisa is now expected to regulate and update its rules to guide the registration of products under investigation. But in any case, the legal framework is very positive in speeding up analysis and harmonizing the Brazilian regulatory environment with good international practices in clinical research.

The legal framework is very positive in speeding up analysis and harmonizing the Brazilian regulatory environment with good international practices in clinical research."

Rubens Granja

Anvisa recently issued a rule allowing some types of laboratory tests to be carried out in pharmacies. Does this permit have the potential to generate partnerships and movement in the market?

Granja: Players with divergent interests have approached us about RDC 786/2023. I think it is a topic that will have repercussions later this year. We have been receiving inquiries from both pharmacy chains that want to enter this market and agents that carry out laboratory tests or at least collect them. We have also received inquiries from large laboratory chains that now have a new competitor and are trying to understand how this dynamic will work. Perhaps this will generate some kind of market movement, even M&A. Laboratories will want to gain capillarity.

However, the rule places limitations. Not every type of test can be carried out in this type of environment.

Materagia Imperatriz: Pharmacy companies are committed to implementing the new standard and have already seen a significant increase in the range of their services. Laboratories have also been working on the issue, structuring how this can work in different environments, because the type of treatment is different. The new rule would authorize pharmacies and drugstores to carry out clinical analysis tests using primary biological material, provided that the analysis steps are carried out in the establishment itself and that no specific instrument is needed in order to interpret the results. Analyses that require greater complexity, including being carried out in another environment, could be carried out through the contractual arrangements and partnerships that the regulations provide for.

Granja: There is an initial euphoria on the part of pharmacies and drugstores to enter this market, but there is a different kind of expertise. Simpler tests - flu confirmations, for example - have already been learned. The next leap, I believe, will be through partnerships. I have seen this movement in conversations with clients who are at both ends, there is synergy.

What are the sector's points of focus that could lead to litigation in the coming years?

Ana Carolina Utimati: The market is a little tense about the tax reform, especially since the government's idea is that there should be no more tax incentives. But in the end, the government brought forward a discussion with Law 14.789/2023, which changed federal taxation on ICMS incentives. The rule changed the way in which investment grants are excluded from the basis for calculating Corporate Income Tax (IRPJ) and Social Contribution on Net Profits (CSLL). This does not just apply to the health sector, but has a very strong impact on the pharmaceutical industry.

This year, we will see taxpayers arguing about how this applies and whether this new rule is applicable. There is a decision by the Superior Court of Justice (STJ) talking about the taxation of presumed credit and how much this new rule changes the Court's previous decision.
This discussion ended up going ahead of the reform, because it is really what is been taking effect for companies since January. It is the most urgent issue at the moment.

Materagia Imperatriz: In the supplementary health sector, we see unpredictability and legal uncertainty caused by various factors. Firstly, in the legislative framework itself, there is a scenario of uncertainty due to the difficulty in predicting the coverage that operators must provide.

We have the ANS rite of updating the list of health procedures and events, which is one of the fastest processes for incorporating technologies in the world and precedes stages of technical evaluation and cost-effectiveness.

In the supplementary health sector, we see unpredictability and legal uncertainty as a result of the difficulty in predicting the coverage that operators must provide."

Maira Materagia Imperatriz

We also have a law [14.307/2022] that stipulates that if a technology is incorporated into the SUS, it must be automatically included in the ANS list within 60 days. There is a very different analysis of what is evaluated by the SUS versus what the impact is, from a technical and economic point of view, for the supplementary health sector. For example, the social participation stage provided for in the incorporation rite and the factors that make up the cost and effectiveness analyses, which from the point of view of the supplementary health sector are important elements.

The new law [Law 14.454/2022] has brought instability to the sector because it excludes the ANS from the competence to be part of the technology incorporation process. The Agency is excluded from any stage of technical evaluation and social participation. There is only one doctor who defines what should be indicated for the patient, as long as they observe certain conditions, which are very broad and generate double interpretations. It requires a technical assessment of the effectiveness and accuracy of the patient's conditions. Who is going to do that? Is it the operator? Is it the doctor?

The new law [Law 14.454/2022] has brought instability to the sector because it excludes ANS's competence to be part of the technology incorporation process."

Maira Materagia Imperatriz

Secondly, we have a history of significant litigation when it comes to health. Judicialization in Brazil contributes greatly to the scenario of legal and financial insecurity in the sector. The Judicial branch does not take part in the technical process, but it is often called upon to grant certain coverage for specific cases, and to judge the constitutionality of strategic laws for the sector. We know that there is also an important social and moral issue when we talk about the right to health.

Systemic fraud is also a vulnerability. Both users and healthcare establishments contribute to losses due to fraud. Operators have tried to combat this through various mechanisms, such as awareness policies, internal protocols and the structuring of sectors to detect possible fraud, legal initiatives against potential fraudsters, among others.

Not least important is the increase in medical inflation costs, boosted by high investments in new technologies, which also generate vulnerabilities.

How do you assess the scenario regarding the ANS list of procedures?

Materagia Imperatriz: Currently, the scenario regarding the ANS list of procedures continues to face a series of discussions and uncertainties, above all as a result of the validity of the New List Law [14.454/2022]. This instability has generated important movements in the health ecosystem, both for health plan operators and beneficiaries, and even for other stakeholders (such as health service providers, etc.).

Within the scope of the ANS, the agency has already declared that it does not have the competence to regulate issues relating to the fulfillment of the requirements set out in the New List Law. In the judicial sphere, the STJ recently heard three appeals that dealt with the List, in which it was decided that the respective plaintiffs were entitled to the extra List coverage sought. We may also see developments in the Supreme Court, as the

constitutionality of the New List Law is being challenged by health plan operators in a Direct Action for Unconstitutionality [7.265].

In the legislative sphere, we also have initiatives in this regard, in particular the possible approval of Bill 7419/2006, known as the Health Plans Bill, in the Chamber of Deputies. As long as we do not have a clearer legal definition of the issue, the scenario of the ANS list of procedures will continue to have a significant impact on the sector.

As long as we do not have a greater legal definition of the issue, the scenario of the ANS list of procedures will continue to have a significant impact on the sector."

Maira Materagia Imperatriz

What are the sector's main challenges when it comes to product pricing?

Granja: The main points are price and judicialization because they interfere with the definition of the budget. We are seeing an increasing trend towards the arrival of advanced and gene therapies, as well as very expensive products. The issue of price fixing still brings a lot of discussion in CMED [the Medicines Market Regulation Chamber]. CMED's agenda for this year includes the revision of Resolution 2 on product pricing. Today, there is no prospect of a conclusive decision that will settle the issue. The truth is one: the products are expensive, have a very significant impact on people's health and have no substitutes. The long-term tendency is for the government to negotiate bilaterally with companies that put new products on the market, anticipating legal disputes.

Today, there is no prospect of a decision to settle the pricing of very high-cost products. The tendency is for the government to make bilateral negotiations that put new products on the market."

Rubens Granja

There is also the impact of this on the Judicial branch. There are some STF actions focusing on judicialization. One of the open issues is very expensive therapies. Last year, monocratic decisions were issued ordering the supply of a drug that would cost R$1 million per patient. It is an important issue, but still far from being settled.

What do you highlight in terms of the regulatory agenda for 2024?

Materagia Imperatriz: At the ANS, we are talking about the regulatory agenda for 2023 to 2025. Among the topics to be addressed, I would highlight the following: (i) improving the relationship between health insurance companies and beneficiaries; (ii) improving the population's access to health insurance; and

(iii) improving supplementary health with the Brazilian Unified Health System (SUS).

In addition, we know that medical practices and claims end up having a significant impact on the pricing of health plans. Simplifying some of the economic and financial rules that are expected of operators is on the regulatory agenda, and there have already been normative acts in this regard. By the end of 2024, an even greater simplification of what is required of operators is expected, in an attempt to retain them in the market and ensure the sector's longevity.

For 2024, an even greater simplification of what is required of operators is expected, in an attempt to retain them in the market and ensure the sector's longevity."

Maira Materagia Imperatriz

Open Health is also on the regulatory agenda with the recent launch of the Connect SUS program, which became SUS Digital. The intention is to integrate health information from the public system and the private system to ensure that the beneficiary or patient has access to all their health data - but with security in the exchange - and so that operators can price their market more effectively. At the end of this year, current ANS president Paulo Rebelo's term ends. His intention is to get the house organized before he passes the baton.

Granja: Anvisa has just published a rule dealing with the admissibility requirements for registration application reviews for foreign regulatory authorities. Until then, the issue was dealt with in a technical note. The analyses of some foreign authorities will now be accepted in Brazil for registration purposes, which should greatly speed up the analysis of some products.

The analyses of some foreign authorities will now be accepted in Brazil for registration purposes, which should speed up the analysis of some products considerably."

Rubens Granja

Ahead, I see the revision of the medical cannabis standard. It is important that it comes back to the fore because most of the products on the market have provisional registrations and are pending clinical research. The truth is that there has been very little progress in terms of clinical research into cannabis-based products in the world. Companies ended up relying on permissive regulations not only in Brazil, but around the world. They ended up investing little in research that showed more concrete results. The permits, which were valid for five years, are expiring. In order to obtain definitive registrations, companies must submit research. It's a problem for the sector. Medical cannabis is a reality, so removing the product from the market, even if it makes perfect technical sense, has social impacts.
The tendency is for the rule to be revised, with some transitional rule.

INTERVIEW

It is important that the review of the medical cannabis regulation comes back to the fore because a large number of products on the market have provisional registrations and are pending clinical research.”

Rubens Granja

We have made progress in the field of pesticides. The legal framework (Law 14.785/2023) was approved with vetoes. We need to deliberate on the vetoes, which are very important. But it is a regulation that greatly speeds up the approval process for pesticides. What is on the regulatory agenda is the revision of the pesticide advertising standard, which is totally in harmony with the new regulatory framework. It is an issue that needs to move forward because we are likely to see an exponential increase in the approval of pesticides. In the past, it took up to eight years for a pesticide to be approved in Brazil. With the new rule, there is a possibility of approval in two months to two years.

There are those who say that Anvisa may have had some of its competence diminished in the legal framework, which is very questionable in my view. The fact is that the Agency has included the regulation of advertising and inspection of pesticides on its regulatory agenda.

Of importance to the consumer on the agenda, there is the revision of the regulation of products intended for aesthetic procedures with dermal action. It is a very controversial issue at Anvisa. The term "dermocosmetics", which is widely used in everyday life, does not exist from a regulatory point of view. There are "cosmetics" and "medicines". Anvisa is aiming to regulate "dermo-cosmetics".

Stay ahead of the market: check out the opportunities and points of attention in the Life Sciences sector

Opportunities

- Contracts and partnerships for the provision of services and supply of products with investments from the Health PAC;
- Opportunities for hospitals and laboratories to enter into partnerships and think about innovative models, moving away from the traditional fee-for-service;
- Partnerships between large laboratories and drugstore chains to carry out tests;
- Attracting investment for clinical research with human subjects based on the new legal framework (Law 14.874/2024);
- Advances in the economic and financial requirements of operators to guarantee greater flexibility in the pricing of health plans.

Points of attention

- Drug pricing;
- Uncertainty over the list of treatments, exams and surgeries to be covered by health plans;
- Anvisa's review of the rules on medicinal cannabis;
- Discussion on the applicability of Law 14.789/2023, which changed federal taxation on ICMS incentives.

ABOUT LEFOSSE

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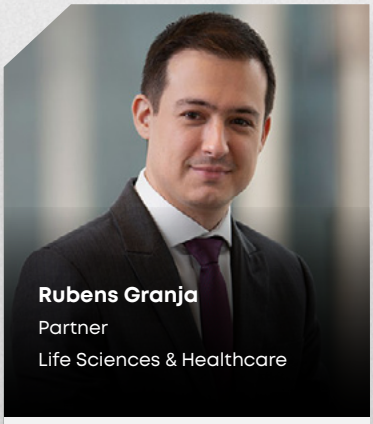

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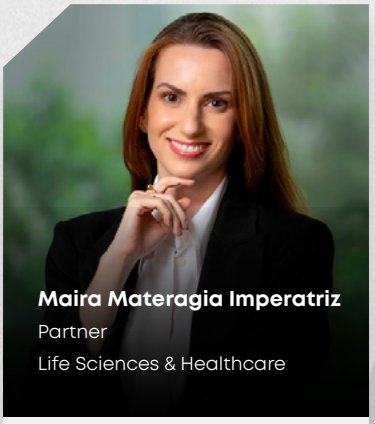

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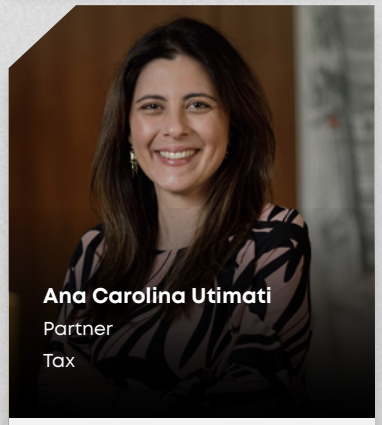

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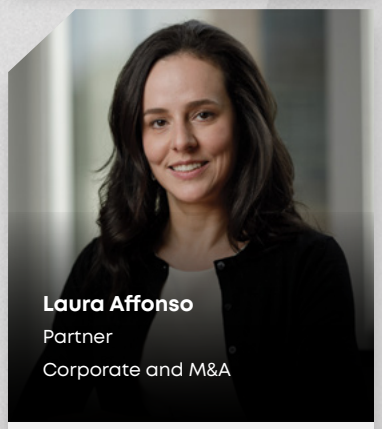

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