Life Sciences

Retrospective 2024 and

Trends 2025

Lefosse

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Context
2024

New PDP framework and PDIL framework

In June 2024, the Ministry of Health (MoH) published Ordinances No. 4,472/2024 and No. 4,473/2024, which regulate, respectively, the Productive Development Partnership Program (PDP) and the Local Development and Innovation Program (PDIL).

Ordinance No. 4,472/2024 introduced important changes in relation to the previous PDP model, such as (i) the inclusion of the history of the products internalization of products in the portfolio of the Public Institution (IP) or the Scientific, Technological and Innovation Institution (ICT) as a criterion for classifying PDP project proposals, and (ii) the possibility of adjusting the price of the product that is the subject of the PDP, considering the price variations in national and international markets.

While the PDP Program focuses on strengthening the national industry through the transfer of health technologies already consolidated and owned by private companies, the PDIL aims to reduce the productive and technological vulnerability of the Unified Health System (SUS) by fostering the local development of innovative solutions. Ordinance No. 4,473/2024 (PDIL) details how this new approach will work, defining important aspects such as (i) the instruments that will be used to implement PDIL, and (ii) the criteria for evaluating PDIL project proposals.

The publication of these regulations was highly anticipated by the sector and adds to the government's actions since 2023 to resume the development policy of the Brazilian Health Economic-Industrial Complex (HEIC).

Following the publication of the ordinances, the Ministry of Health set a deadline of September 30, 2024 for the submission of project proposals for the PDP and PDIL programs.

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Context
2024

New legal and regulatory framework for clinical research

After almost a decade of discussions in the National Congress, 2024 marked the sanction of Law No. 14,874, which establishes a legal framework for clinical research in Brazil. This new legislation introduces important advancements for the sector, in particular the definition of clear rules for the continuation and conclusion of post-clinical trial treatment, including the creation of a post-study access plan, which must be approved by the Research Ethics Committee (CEP) before the research begins.

In addition, the law establishes shorter deadlines for the ethical and regulatory analysis of protocols, enhances of participants protections - such as guaranteeing the anonymity of personal data and prohibiting remuneration or the granting of advantages to participants -, and provides for the creation of the National Research Ethics System.

As part of the proposal to reduce bureaucracy and speed up the clinical research process in Brazil, the Brazilian Health Surveillance Agency (Anvisa) has also took significant steps with the publication of RDC No. 945/2024. This standard establishes guidelines and procedures for carrying out clinical trials with the aim of registering new drugs in the country. Among the key innovations is the possibility for the sponsor to import the investigational product for research before Anvisa has concluded its analysis of the dossier. In addition, the resolution introduces a more agile and flexible procedure for assessing dossiers for the clinical development of drugs and clinical trials, based on risk and complexity analysis.

With these changes, 2025 is expected to be a year of growing investment and new opportunities in Brazil's clinical research sector. The new rules aim not only to simplify processes, but also to position Brazil as a more attractive destination for conducting clinical research, promoting the advancement of science and innovation in the country.

Context
2024

Supply of drugs not incorporated into the SUS

In September 2024, the STF concluded a long-standing debate regarding the provision of drugs not incorporated into the SUS through judicial orders. In different rulings, the STF has defined the jurisdiction of the judiciary to hear lawsuits on the subject and has established the criteria that must be followed by the Judiciary when judging claims related to this subject.

As a result of the judgment in Extraordinary Appeal No. 1.366.243 (Theme 1234), the Court was established that when the value of the annual treatment is (i) **equal to** or **greater than** 210 (two hundred and ten) minimum wages, the claims will be dealt with by the Federal Court, (ii) **between** 7 (seven) and 210 (two hundred and ten) minimum wages, the claims will be dealt with by the State Court, the Union will have to reimburse 65% of the expenses due to the convictions of the states and counties, (iii) in the case of drugs not registered with Anvisa, the jurisdiction of the Federal Court is maintained, and (iv) oncological drugs not incorporated will have a reimbursement percentage of 80% by the Union, in lawsuits that have been filed by June 10, 2024, if the cost exceeds 7 (seven) minimum wages.

In turn, the judgment of Extraordinary Appeal No. 566,471 (Theme 6) established the criteria for the supply, via lawsuits, of high-cost drugs approved by Anvisa but not incorporated into the SUS. In summary, the STF defined that, in order to be supplied, the drug must be registered with Anvisa and the following requirements met: (i) proof of the administrative refusal to supply it, (ii) no alternative in the SUS, (iii) presentation of robust scientific evidence to support the efficacy and safety of the drug requested, (iv) demonstration of the clinical indispensability of the treatment, as well as proof of the plaintiff's financial inability to afford the product, (v) proof that there has been no request for the drug to be incorporated into Conitec, or, if there has been, that the Commission has denied incorporation or is in arrears in its analysis, and (vi) consultation by the Judiciary with specialists in the health area to ensure that decisions are not made based solely on prescriptions, reports or medical reports presented by the plaintiff.

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In October 2024, the Supreme Court published Binding Precedent No. 61, determining that all court decisions must comply with the criteria established by Theme 6 above. Although the matter has already been settled, its effects will be more strongly felt in 2025, with new court rulings on the subject.

Regulatory trust between Anvisa and foreign authorities

Anvisa has dedicated itself to strengthening international cooperation, exchanging information and implementing mechanisms that promote interoperability and standardization with foreign health authorities.

In this context, in April 2024, Anvisa published Normative Instruction No. 292/2024 (IN), which aims to (i) optimize the Good Manufacturing Practices (GMP) certification process and (ii) define the criteria for recognizing Equivalent Foreign Regulatory Authorities (AREE) in the inspection of drugs, biological products, medicinal cannabis products and active pharmaceutical ingredients (IFA).

The regulation considers as AREE the member authorities of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH). Currently, 42 authorities meet this criterion.

The IN defines three levels of reliance that Anvisa may adopt: (i) **partial relaince**, with a complete analysis of the AREE's inspection report, which may be unilateral, (ii) **full reliance**, with a simplified analysis of the report, also unilateral, and (iii) **mutual recognition**, when Anvisa and the AREE, through a bilateral agreement, accept each other's the inspection report or GMP certificate of the other party.

Although the regulation has been in force since June 2024. In 2025, a significant increase is expected in the number of companies petitioning to Anvisa to request the optimized procedure.

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2024

The normative deadlock of digital package insert regulation

The possibility of replacing physical | packaging inserts with digital ones | remains a controversial topic, widely debated in the sector. Advocates of the digital package inserts argue that it can provide significant benefits, such as the inclusion of illiterate patients and caregivers or those with reading difficulties. However, critics point out that the digital package insert could exclude those who don't have access to the internet, preventing them from accessing important information about drugs.

In response to this debate, Congresswoman Jandira Feghali, from PCdoB/RJ, presented the Bill of Law No. 715/2024, which aims to eliminate the possibility of Anvisa deciding which drugs will have digital or physical package inserts, as provided for in Law No. 11,903/2009. While the Bill is under discussion in Congress, Anvisa has made progress with the implementation of a pilot project, published in July 2024, through RDC No. 885/2024, which establishes transitional guidelines for digital package inserts.

RDC No. 885/2024 allows for the optional waiver of printed package inserts for certain drugs, such as free samples, products intended for healthcare facilities and non-prescription drugs. The digital package insert will be accessible through a platform called the Repository of Electronic Product Information (RIEP), which ensures access to the most up-to-date version of the package insert approved by Anvisa. This regulation will remain in force until December 31, 2026, and may be subject to revision, depending on the progress of the pending Bill in Congress.

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2024

Transparency in the relationship between industry and physicians

In September 2024, the Federal Council of Medicine (CFM) issued Resolution No. 2,386/2024 with the aim of making interactions between the medical profession and the pharmaceutical, medical supplies and equipment industries more transparent to prevent conflicts of interest that could influence medical decisions.

Initiatives to increase transparency in the physician-industry relationship are not new. Globally, the pioneering initiative was the Sunshine Act, a 2010 US regulation that obliges manufacturers of drugs, supplies and health products to report payments made in favor of physicians and teaching hospitals.

CFM Resolution No. 2,386/2024 follows the same logic with the difference that, due to the CFM's scope of action, the obligations and prohibitions are directed only at medical professionals.

The following are considered to be links between the professional and the industry, subject to reporting: formal employment contracts; occasional and/or remunerated service provision; carrying out and participating in research to develop new products; inviting or contracting for remuneration to advertise the company as a paid speaker; acting as a speaker; and participation in Conitec and similar deliberative councils. On the other hand, physicians are expressly exempt from reporting: income and dividends resulting from their investments in shares or quotas in companies in the health sector, as long as it is a purely financial relationship; free samples of drugs and/or products regulated by Anvisa received from companies in the sector; and benefits received by scientific societies and medical entities.

CFM Resolution No. 2,386/2024 will come into force in March 2025, from which point professionals will be obliged to comply with the above rules, under penalty of being subject to administrative sanctions imposed by the CFM.

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2024

Food labeling regulations

With the aim of aligning Anvisa's regulations with the standards established by Mercosur, RDC No. 854/2024 was published, establishing health requirements for metal packaging, utensils, lids and equipment used in contact with food and its raw materials, from production to storage. The new regulation aims to update the list of metallic raw materials allowed for the production of these materials, seeking to harmonize national requirements with the international ones.

Among the main points addressed by the RDC is the concern for the safety of food in contact with aluminum materials and their alloys, especially when these materials are not coated. The rule seeks to mitigate the health risks related to these materials, specifying the types of metals allowed for packaging and equipment, and requiring food to be isolated from undesirable substances and contaminants.

RDC also sets strict limits for impurities present in metallic materials, ensuring that there are no harmful changes to the sensory characteristics or composition of the food. This regulation aims to increase the safety and quality of food products, protecting public health and promoting compliance with international standards in the sector.

Companies had 180 days from the entry into force of the rule (May 2024) to adapt to the requirements set forth in the RDC. Thus, since November 2024, companies have adopted measures to comply with these requirements and must continue to ensure compliance throughout 2025.

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2024

Regulation of the Agricultural Self-Control Law

Law No. 14,515/2022 (Self-Control Law) was enacted in December 2022 with the aim of modernizing the agricultural inspection system, which was previously conducted exclusively by the State. The new model is hybrid, with greater participation from the private sector. Under this law, companies in the agricultural sector have to implement self-control programs to ensure the safety, quality, identity and harmlessness of their products. The role of the Government is to monitor whether companies are complying with the requirements of these programs.

The year 2024 was marked by various government initiatives to ensure the implementation of this model and the changes introduced by the Law, such as a new appeals system for sanctioning agricultural administrative processes.

One of the key milestones was the publication, in August 2024, of Decree No. 12,126/2024, which regulates the self-control programs of regulated private agents and the Agricultural Defense Compliance Incentive Program for the animal-origin and animal feed products sectors.

According to the Decree, self-control programs must be implemented, monitored and maintained by companies, guaranteeing the safety, quality and harmlessness of agricultural products. These programs must include systematized and auditable records, provisions for batch recalls, self-correction procedures and the adoption of good practices guidelines.

The Agricultural Defense Compliance Incentive Program allows establishments to periodically share operational data on quality with the agricultural inspection authorities, in exchange for benefits and incentives. The Decree details the requirements for voluntarily joining the program and for maintaining participation.

In addition, the Decree establishes that agricultural inspection will be carried out at any stage of the production chain, based on risk management

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2024

principles, aiming for uniformity, isonomy and transparency in the relationship with companies.

Finally, the Self-Control Law has influenced the drafting of specific regulatory acts for the inspection of products regulated by MAPA. One example is Decree No. 12,031/2024, which adapts the inspection of products intended for animal feed to the new model introduced by the Self-Control Law.

New legal framework for pesticides

The publication of Law No. 14,785/2023, effective as of 2024, brought significant changes to the pesticide sector in Brazil, establishing a new regulatory framework that replaces Law No. 7,802/1989, which had been in force for more than 30 years. The new law aims to modernize and accelerate the process of registering, marketing and using these products, which are essential for agriculture. One of the main changes is the definition of a maximum period of 24 months for the analysis and approval of the registration of new pesticides, which represents an important improvement in terms of efficiency and predictability for companies in the sector. In addition, the centralization of the registration process at the Ministry of Agriculture and Livestock (MAPA) makes it easier for companies to interact with the regulatory authority, promoting a greater speed and transparency in approvals.

The new legislation also provides for a more agile process for reassigning the safety of products, which allows companies to update their portfolios more quickly and in line with international trends. This is a significant benefit for companies seeking to constantly innovate, as they will be able to launch new products more quickly onto the market. For the sector, the expectation is that companies will be able to act more competitively, with a more efficiently updated product portfolio, keeping up with technological innovations and better meeting the needs of agribusiness.

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2024

In terms of impact, the new legal framework represents an important advance for the sector, as it reduces bureaucracy and provides a more predictable and agile process for companies that rely on new products approvals to serve the market. This should result in the arrival of more modern and efficient technologies in Brazil, helping the country to remain competitive on the global stage.

What should change in the market in 2025?

Sanction of the bio-inputs Law

The Brazilian agricultural sector has been advancing in its pursuit search for more sustainable practices, with the growing use of bio-inputs – which are products and technologies of animal, vegetable or microbial origin used to fertilize the soil and protect against pests – standing out. Although already in use, these products lacked a specific regulatory framework, operating under different regimes depending on their application, such as pesticides or fertilizers. The lack of specific regulations has created challenges for the sector, especially regarding the production of bio-inputs under the *on-farm* management model, in which the producer manufactures the products for personal use, without commercial purposes.

At the end of 2024, more specifically on December 23, recognizing this need for regulation, the government enacted the long-awaited Law No. 15,070/2024, published on Christmas Eve, which regulates the production, use and marketing of bio-inputs. The Law sets out to establish a clear regulatory framework, especially with regard to production under the *on-farm* system.

Generally speaking, it can be said that Law No. 15,070/2024 brings balance by proposing a more flexible regulatory regime for on-farm management, exempting products produced exclusively for personal use from registration, but establishing that a future federal regulation will define whether the production for personal use must be supported by a qualified technical manager. This approach seeks to ensure that the production of bio-inputs for personal use does not compromise product safety, while not making the production model adopted by many rural producers unviable.

The new regulatory regime promises to bring greater clarity and legal certainty to the sector, allowing Brazil to continue advancing in the sustainable development of agriculture and livestock. The first few months of 2025 will be important for us to assess how the sector will adapt to this new legal framework.

What should change in the market in 2025?

Cannabis market awaits regulation for hemp cultivation

In November 2024, the market experienced a significant breakthrough regarding activities involving the use of hemp for medicinal purposes. The Superior Court of Justice ("STJ") has authorized the import and cultivation of the plant for the production of drugs and other by-products for exclusively medicinal, pharmaceutical or industrial purposes.

The decision was the result of a vote by Minister Regina Helena, who based the release on the existence of several scientific studies indicating the beneficial effects of using hemp, which has a low THC (*tetrahydrocannabinol*) content, for various diseases, especially neurological ones.

In the Minister's words, the lack of regulation could prevent the development of a sector that could offer low-cost therapies for patients, as well as creating jobs and promoting scientific research.

Thus, a deadline of six months was set for Anvisa or the Federal Government to define rules for importing and growing cannabis sativa with a low THC (*tetrahydrocannabinol*) content. A possible definition of these rules may result in the revision of Anvisa's Resolution RDC No. 327/2019, which currently prohibits the import of *Cannabis spp.* plants and plant parts. Relevant progress on the matter is therefore expected in the first half of 2025.

What should change in the market in 2025?

Anvisa must continue with the sandbox to boost innovation

The Brazilian Health Surveillance Agency (Anvisa) has taken an important step towards innovation in the health sector. With the emergence of new business models and innovative technologies in the health sector, Anvisa is discussing the establishment of a flexible and innovative regulatory environment to ensure the safe development of new solutions, without losing sight of its institutional purpose of promoting the protection of the population's health.

The topic is part of the Regulatory Agenda 2024-2025 and aims, in practice, to contribute to the development of new services and promising health technologies in Brazil, by providing to the interested parties – including startups – a controlled space for testing and validation before their definitive entry into the market.

With the launch of the Public Call notice No. 11/2024 and the Call for Public Contributions (CPC) No. 9/2024, Anvisa began a process to collect contributions from society regarding the Partial Report of the Regulatory Impact Analysis (AIR) which addresses the creation of its Experimental Regulatory Environment model, also known as the Regulatory Sandbox.

The deadline for submitting contributions closed on October 11, 2024, and included the participation of various sectors of society, including citizens, health professionals, entrepreneurs, startups and government authorities. It is currently estimated that Anvisa will continue to draft a resolution on the subject, to be presented to the Collegiate Board and, if approved, published in the Brazilian Official Gazette, making the launch of the regulatory framework official.

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What should change in the market in 2025?

Progress of regulations on the use of AI and the impacts on health

Bill of Law No. 2,338/2023, presented by Senator Rodrigo Pacheco, seeks to regulate Artificial Intelligence (AI) in Brazil, with a focus on systems classified as high risk. It proposes a set of obligations for AI agents, to protect rights, prevent irreversible damage, and discrimination, and protecting personal data. One of the main points of Bill of Law No. 2,338/2023 is to classify the health sector as high-risk.

The inclusion of health as a high-risk area in Bill of Law No. 2338/2023 may lead to conflicts with the regulations of the Brazilian Health Surveillance Agency (Anvisa), which classifies certain software as medical devices (SaMD) and establishes specific criteria for risk classification.

The bill was approved by the Federal Senate in a vote held on December 10, 2024, and now proceeds to the Chamber of Deputies for consideration.

New debate of Anvisa's competence to ban additives in smoking products

In 2024, the Federal Supreme Court (STF) began the general repercussion trial (Theme No. 1252) of an appeal (ARE No. 1348238) that discusses the legitimacy of Anvisa to prohibit the use of additives, such as flavorings, in smoking products derived from tobacco. This debate has already been analyzed by the STF in 2018, during the judgment of ADI No. 4,874, when the Court validated Anvisa's RDC No. 14/2012. However, as STF did not give binding effect to the decision, the marketing of products with additives continued ongoing, supported by injunctions granted by the Federal Justice Courts, at the request of entities that represent the sector.

What should change in the market in 2025?

The current judgment has the potential to bring a definitive and binding solution to the issue, since it takes place under the general repercussion system. The STF may reaffirm its position that Anvisa has the power to ban the use of additives in smoking products or, on the other hand, it may change its understanding, denying the agency the regulatory authority for such a ban. The vote of the rapporteur, Justice Dias Toffoli, was in favor of Anvisa's authority to restrict the addition of additives, but the trial was interrupted on November 12, 2024, after Justice Alexandre de Moraes asked to review the case.

The trial is expected to resume in the first half of 2025, when Justice Moraes' 90 working day review period expires. The STF's decision will have significant implications for the tobacco-derived smoking products sector, resolving the controversy over the scope of Anvisa's role in regulating these products.

CMED - review of drug pricing regulations

Since 2021, there have been discussions about revising the pricing drugs regulations established by the Drug Market Regulation Chamber (CMED). The main criticism of CMED Resolution No. 2/2004, which has regulated the pricing of drugs since 2004, is that it is outdated, without adequate criteria to deal with new market realities, such as the pricing of products with incremental innovations and advanced therapies, which naturally involve high production costs.

Although there is a growing expectation that the pricing regulations will be updated as early as 2025, any evidence of a concrete change is still limited. In 2024, CMED representatives indicated progress in the internal review process, and the body has promoted initiatives to improve other areas of its regulation, such as the public hearing held on December 3, 2024, to present proposals for revising its internal regulations.

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What should change in the market in 2025?

These movements suggest that the updating of the pricing regulations is underway, but it still depends on further definitions for it to become effective.

Market thermometer

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Opportunities

- **Impacts of the tax reform on the health sector:** the version of the Tax Reform Bill (PLP No. 68/2024) approved by the Chamber of Deputies on December 17, 2024, and sent for presidential sanction, provides for a 60% reduction in the tax rates for drugs and a zero tax rates for 383 medicines listed in its Annex XIV.
- **Signing of Terms of Commitment:** on September 23, 2024, Anvisa opened a public consultation regarding the signing of Terms of Commitment for the registration or post-registration of drugs and biological products. The Agency received contributions until November 30, 2024, and it is expected that the topic will advance on Anvisa's regulatory agenda in 2025.

- **Cannabis in the pet market:** changes to Ordinance No. 344/1998 will allow MAPA to regulate cannabis-based veterinary products for sale in Brazil, additionally veterinarians will be able to prescribe cannabis-based drugs registered with Anvisa.

Points of attention

- **Presidential veto on the Clinical Research Law:** in 2025, Congress is expected to deliberate on whether to uphold or overturn the presidential veto on provisions of the Clinical Research Law (Law No. 14,874/2024), among them the five-year requirement for continuing to supply the drug free of charge after the end of the study.

Market thermometer

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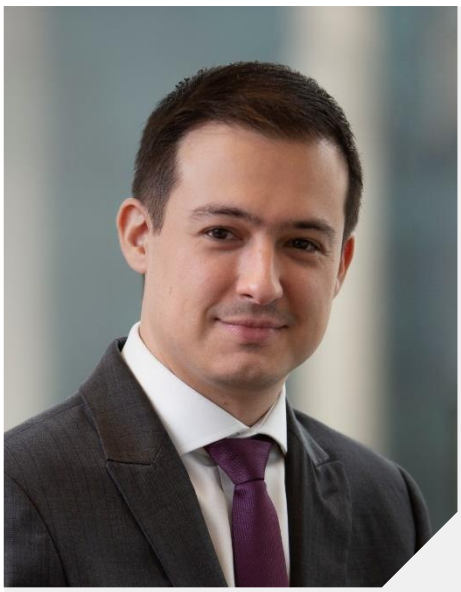
- **Technical assistance for medical equipment:** the Chamber of Deputies is expected to proceed with a bill of law that seeks to authorize the direct importation of medical devices components and accessories by technical assistance companies.

- **Changes in Anvisa's Presidency and Board of Directors:** the end of 2024 marked the end of the terms of Anvisa's president and directors. The President of the Republic published an order naming Mr. Leandro Pinheiro Safatle to the position of Director-President, of Ms. Daniela Marreco Cerqueira to take over as Second Director, and Mr. Diogo Penha Soares to take over as Fifth Director on April 1, 2025 (when Mr. Alex Machado Campos' term, who had resigned, ends). While the Federal Senate is considering the nominations made by the Presidency of the Republic, Mr. Rômison Rodrigues Mota will serve as interim president of Anvisa.

What does our partner say?



Rubens Granja
Partner in the Life Sciences & Healthcare practice

“After a 2024 marked by significant advancements and the consolidation of crucial topics for the health area, 2025 promises to be a year of strategic debates and essential definitions. On the regulatory front, several relevant Bills of Law are in advanced stages of being processed, requiring heightened attention from the sector for swift adaptation to the planned changes. In addition, public-private investments in the health economic-industrial complex are expected to intensify, with significant initiatives from the Ministry of Health to establish new Productive Development Partnerships. The sector must prepare itself to seize these opportunities by structuring sustainable and legally secure projects.

Another key highlight expected for 2025 is the operationalization of the new legal framework for clinical research, which could attract a greater volume of studies to the country. In this context, the health industry and clinical research centers have already been strengthening partnerships and developing innovative projects, aiming to execute their initiatives over the next year. This promising scenario points to a period of growth and innovation, reinforcing Brazil's leading role in the health sector.”

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