



LIFE SCIENCES

DEMAREST

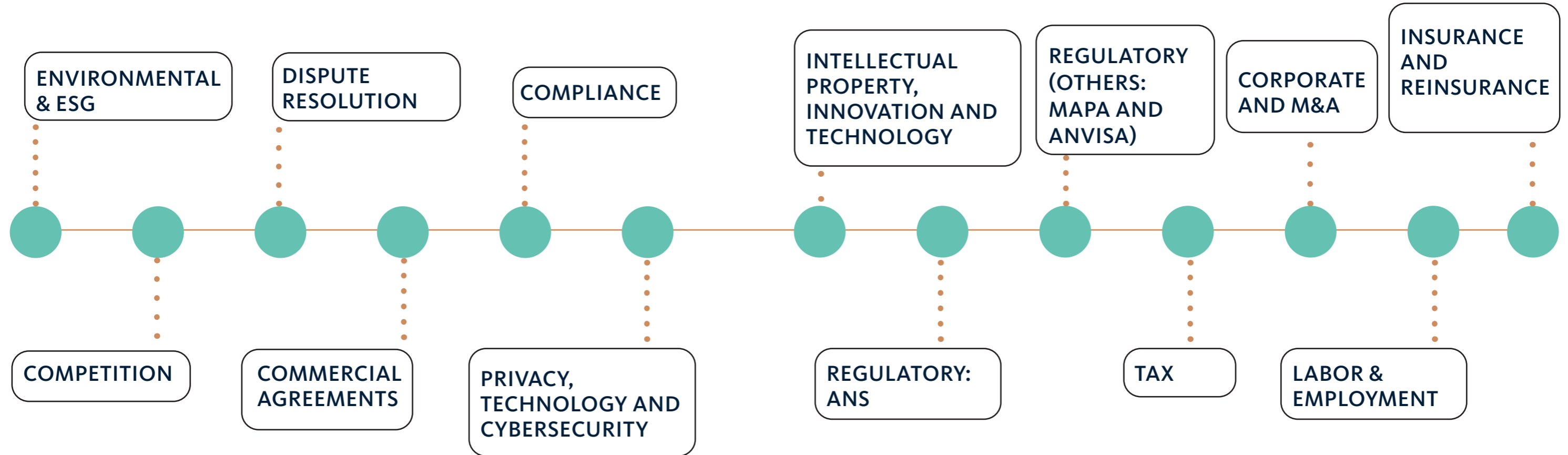


SUMMARY

OUR MULTIDISCIPLINARY TEAM.....	4
ANVISA AND PUBLIC HEALTH OVERSIGHT.....	7
MAPA - AGRICULTURE AND LIVESTOCK.....	10
PROFESSIONAL BOARDS IN DIFFERENT SECTORS.....	14
COMPETITION LAW.....	16
COMPLIANCE & INVESTIGATIONS.....	17
DISPUTE RESOLUTION.....	18
LABOR AND EMPLOYMENT.....	20
COMMERCIAL AGREEMENTS.....	21
TAX.....	22
PRIVACY, TECHNOLOGY AND CYBERSECURITY.....	24
INTELLECTUAL PROPERTY, INNOVATION AND TECHNOLOGY.....	25
ENVIRONMENTAL.....	27
ESG.....	28
CORPORATE/M&A.....	31

OUR MULTIDISCIPLINARY TEAM

11 INVOLVED AREAS



BRAZILIAN NATIONAL HEALTH REGULATORY AGENCY (“ANVISA”) AND PUBLIC HEALTH OVERSIGHT

MAIN REGULATED PRODUCTS AND SERVICES



Foods



Cosmetics



Health services



Agrochemicals



Laboratory/
Analytical
Services



Tobacco



Medicines



Health
Products



Sanitizing Products



Blood, tissue, cells, organs
and advanced therapies

BUSINESS ESTABLISHMENTS



Retail
and Bulk
Commerce



Health
Techs



Shipping
Companies



Distributors



Importers
and exporters



Manufacturers



Clinical research labs,
hospitals and laboratories



Companies and products
related to agribusiness

BRAZILIAN NATIONAL HEALTH REGULATORY AGENCY (“ANVISA”) AND PUBLIC HEALTH OVERSIGHT

HOW WE CAN HELP



REGULATORY CONSULTING

Regulatory consulting on various topics (including, but not limited to, ANVISA, local public health oversight, the Brazilian National Health Council (CNS), the Medicine Market Regulation Chamber (CMED), the Brazilian National Committee for Incorporation of Technology in the Brazilian Unified Health System (CONITEC/SUS), professional boards (medical, pharmaceutical, nursing, nutrition, among others).



AUDITING AND NEGOTIATIONS

Advice on structuring and due diligence of M&A agreements, corporate restructuring and other corporate and commercial operations.



REGULATORY COMPLIANCE

Regulatory compliance with digital health initiatives and new products and partnerships.



IMPORT AND EXPORT

Assisting on matters concerning import and export of products.



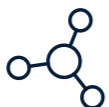
CONTRACTS

Drafting and negotiation of highly complex commercial agreements.



MARKETING AND ADVERTISING

Assisting in matters concerning the advertising and marketing of regulated products.



ETHICS AND COMPLIANCE

Assisting on matters related to compliance and professional ethics in the health sector.



TRANSFER OF REGISTRY

Assistance in the process of transferring the registry of products before ANVISA.



ADMINISTRATIVE PROCEDURES AND AUDITS

Acting in administrative proceedings and audits carried out by health authorities within the federal, state and municipal scopes.



OBTAINMENT OF REGULATORY LICENSING

Advising on the obtainment of permits, authorizations, licenses, registrations, permissions and certificates issued by federal, state and local government health entities (according to the technical classification of the license).



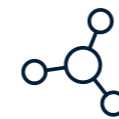
CONTRACTING AND PARTNERSHIPS

Assistance in public bids, Public-private Partnerships (PPPs) and Product Development Partnerships (PDPs) in the health sector, assisting in tendering procedures before the Brazilian Ministry of Health.



ANS - SUPPLEMENTARY HEALTH

HOW WE CAN HELP

**STRUCTURING AND DUE DILIGENCE**

Participation in proceedings of structuring and due diligence of M&A operations, corporate restructuring and corporate restructuring of portfolios involving health care plan operators and benefit administrators.

**TRANSFER OF REGISTRY AND PORTFOLIO**

Representation in proceedings involving the request for transfer of register and portfolio or corporate control over healthcare plan operators and benefit administrators.

**INTERVENTION, LIQUIDATION AND SALE**

Representation in cases involving financial and/or operational intervention, extrajudicial liquidation and compulsory sale of portfolio.

**MODALITIES OF PRODUCTS**

Assisting on the development of new models for products subject to ANS regulations, in addition to forming partnerships aimed at cost reduction.

**SUSPENSION OF TRADING**

Assisting on situations involving suspensions in the commercialization of products.

**AUDITS**

Assistance in audits.

**CONTRACTS**

Drafting and negotiation of commercial agreements.

**CONSULTING**

Regulatory consulting on matters related to supplementary health.

**REGULATION**

Collaborating with ANS in regulatory matters.

**REGISTRATION**

Registration with the ANS of operators and administrators of products and benefits.

**PRELIMINARY INVESTIGATION NOTIFICATIONS**

Representation in (a) Preliminary Investigation Notifications (NIPs), which can potentially result in suspension of commercialization of plans; and (b) in violation notices served to healthcare plan operators/administrators.

MAPA - AGRICULTURE AND LIVESTOCK

BUSINESS ESTABLISHMENTS AND PRODUCTS SUBJECT TO MAPA REGISTRATION

	Plant-based products		Industrial additives for animal feed (acidulants, preservatives, coloring agents, vitamins, minerals, probiotics, etc.)
	Agrochemicals and pesticides		Supplements, animal production enhancers, antiseptic agents, disinfectants for environmental use or for equipment and livestock facilities
	Fertilizers, inoculating agents, soil correctors		All products, whether they are used for animals or their habitat, that protect, restore or modify their organic and physiological functions, in addition to products for animal hygiene and grooming
	Livestock supplies		All chemical, biological, biotechnological or manufactured substances, whose use is carried out individually or collectively, directly or incorporated into food, and whose purpose is to prevent, diagnose, treat or cure animal illnesses
	Animal feed products		
	Businesses and goods related to agribusiness, the veterinary market, beverages, wines and vinegars		

BUSINESS ESTABLISHMENTS

	Producers		Warehouses/ Depots		Distributors
	Importers and Exporters		Distributors that sell in bulk		
	Businesses and goods related to agribusiness, the veterinary market, beverages, wines and vinegars				

HOW WE CAN HELP

	MODALITIES OF PRODUCTS Assistance on the development of new models for products subject to MAPA regulations.		COMPLIANCE Assessing the product's compliance (label, packaging, etc) with the applicable regulations.
	CONTRACTS AND NEGOTIATIONS Drafting, review and negotiation of contracts typical of the sector.		SUPPLY OF PRODUCTS IN BID PROCEEDINGS Assisting on tendering procedures for the supply of products.
	STRUCTURING AND DUE DILIGENCE Participation in structuring and due diligence proceedings for M&A operations and corporate restructuring involving products and foods regulated by MAPA.		SUSPENSION OF TRADING AND SANITARY CERTIFICATION Assistance in situations involving suspensions in the commercialization and sanitary certification of products.
	REGULATION Collaborating with MAPA in regulatory matters.		AUDITS Assisting on audits.
	DOMESTIC TRANSPORT, IMPORT AND EXPORT Regulatory consulting on matters concerning domestic transport, import and export of products.		AGRICULTURE, LIVESTOCK AND FOOD SUPPLY Regulatory consulting on matters related to agriculture, livestock and food supply.
	NOTICES, SUMMONS AND PUNITIVE ADMINISTRATIVE PROCEEDINGS Representation in Notices of Violation, Tax Summons, Suspension Notices and punitive administrative proceedings that can result in apprehension or disposal of raw materials, suspension of activities, interdictions involving business establishments and revocation of registrations.		

PROFESSIONAL BOARDS IN DIFFERENT SECTORS

PROFESSIONAL BOARDS



Regional Council of Chemistry - IV Region



Regional Council of Biomedical Sciences - 5th Region



Regional Council of Dentistry of the State of Rio de Janeiro



Brazilian Federal Dentistry Council



Brazilian Federal Council of Nursing



Brazilian Federal Medicine Council



Brazilian Federal Pharmacy Council



Regional Association of Pharmacy of the State of Rio Grande do Sul



Regional Medical Council of the State of São Paulo

HOW WE CAN HELP



Representation in administrative proceedings before federal and regional professional boards



Assistance in carrying out and canceling company's and professionals' registrations with the boards



Assessment of regulatory obstacles and restrictions regarding the development of new products and marketing campaigns



Regulatory consulting on professional Codes of Ethics



Assessment of the companies' good standing before the federal and regional professional boards – within the scope of M&A operations and corporate restructuring



COMPETITION LAW

HOW WE CAN HELP



TRAINING

Carrying out training on competition-related matters based on the applicable legislation and internal guidelines of the company, as well as in case law and known risks of the sector.



COMPLIANCE PROGRAMS

Implementation/review of Competition Compliance Programs based on risk analyses of the sector; Developing or reviewing internal guidelines, such as conduct and competition policies.



MERGERS/ CONCENTRATION ACTS

Drafting merger notices for competition authorities, and assisting in obtaining approvals.



ADMINISTRATIVE AND JUDICIAL DISPUTE RESOLUTION

Representation/defense in proceedings of anti-competitive behavior investigations before the competition authorities, whether as claimant (representative) or defendant (represented), often in collaboration with the dispute resolution and criminal law teams.



LENIENCY AGREEMENTS AND CEASE-AND-DESIST COMMITMENTS

Negotiation of leniency agreements and other agreements with competition authorities and the Prosecution Office.



ANALYSIS OF COMPETITION ASPECTS OF M&A OPERATIONS

Audits and negotiations of M&A agreements, joint ventures, foreign investments in the sector, sale and purchase of assets, cooperation agreements and corporate restructuring.



RISK ANALYSIS

Analysis of competition risks in potential operations of the sector, taking into consideration the development/growth of the industry.



CONSULTING AND LEGAL OPINIONS

Consulting and legal opinions/ memoranda on anti-competitive behavior (unilateral and coordinated conduct), particularly the practices that are most common or most connected to the health sector, taking into consideration the global trend for antitrust authorities to closely monitor the industry.

COMPLIANCE & INVESTIGATIONS

HOW WE CAN HELP



CONSULTING AND LEGAL OPINIONS

Consulting on potential repercussions from acts of corruption and bid rigging, and on conflicts of interests in the relationship with health professionals.



COMPLIANCE PROGRAMS

Implementation/review of Anti-corruption Compliance Programs based on risk analyses of the sector; Developing or reviewing internal guidelines, such as Code of Ethics/Conduct and policies concerning Anti-corruption, Interaction with health professionals, Interaction with government agents, Conflicts of Interests, Donations and Sponsoring, among others.



INTERNAL INVESTIGATIONS

Carrying out internal investigations on potential practices of corruption, fraud, insider trading, among others.



TRAINING

Carrying out Anti-Corruption Compliance training based on the applicable legislation and the company's internal guidelines, as well as on case law and known risks of the sector.



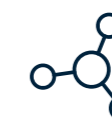
CERTIFICATES OF INTEGRITY / TRANSPARENCY LAW

Assistance in the obtainment of integrity certificates such as the Pro-Ethics Business Seal (Selo Empresa Pró-Ética) and to ensure compliance with Minas Gerais State Law No. 22,440, of December 21, 2016 (Declarasus).



LENIENCY AGREEMENTS AND INDEPENDENT MONITORING

Assistance in negotiating leniency agreements with authorities; Assistance in independent monitoring procedures, whether in the role of monitor or independent consultant for the company.



COMPLIANCE DUE DILIGENCE

Carrying out due diligence on compliance for high risk outsourced hirings (e.g. commercial distributors/representatives), as well as for corporate transactions (M&A, joint ventures, etc.). Drafting/reviewing anti-corruption clauses.

DISPUTE RESOLUTION

HOW WE CAN HELP



AMICUS CURIAE

Representation as *amicus curiae* in actions relevant at the national level.



COMPARATIVE CASE LAW

Monitoring comparative case law on relevant topics.



MEDIATION

Representation in business mediations.



PRE-LITIGATION

Assistance in pre-dispute proceedings.



INTELLECTUAL PROPERTY

Representation in intellectual property actions (trademarks, patents, cultivars, etc.).



INJUNCTIONS

Representation in injunctions against government acts that interfere with the company's rights.



OPINIONS

Drafting opinions on various legal matters.



CIVIL ACTION

Representation in dispute resolution of public civil actions.



TRADE ASSOCIATIONS

Assistance with trade associations.



COMMERCIAL ARBITRATION

Representation in commercial arbitrations against the Government.



LABOR AND EMPLOYMENT

HOW WE CAN HELP



WORKING HOURS

Assessment of working hours practices and identification of opportunities for improvement, with focus on cost reduction within alternatives provided for in the legislation and applicable to the health sector.



TECHNICAL RESPONSIBILITY

Assessment of potential labor-related implications for employees that accept technical responsibilities before third parties.



OCCUPATIONAL HEALTH AND SAFETY

Review of programs such as Environmental Risk Prevention Plan (PPRA), Occupational Health and Medical Oversight Program (PCMSO), Technical Record of Workplace Conditions (LTCAT), among others, with focus on compliance with the applicable regulations and maintaining consistency among all internal documents.



TELEWORK

Review of telework practices based on the best market practices, considering the particularities of the health sector. Drafting documents pertinent to the telework framework.



LABOR & EMPLOYMENT POLICIES

Developing and reviewing internal policies applicable to employees on various topics, such as remuneration, benefits, working hours, use of social media, information security, etc.



MINI AUDIT OF LABOR & EMPLOYMENT PRACTICES

Assistance in the identification of hidden liabilities and opportunities for improvement of the company's labor & employment practices, encompassing proceedings ranging from admission to termination practices.



UNION NEGOTIATIONS

Assistance in collective bargaining negotiations involving various topics, applying our extensive practical experience in developing relationships with unions of the chemical, pharmaceutical and health sectors.

COMMERCIAL AGREEMENTS

HOW WE CAN HELP



CONTRACT MANAGEMENT

Monitoring all phases of an agreement, from drafting contracts to the specific execution. Assistance in all steps up to the termination of a contract.



PRACTICAL EXPERIENCE

We assist various clients in the area and have extensive experience in civil and contractual aspects of such relationships.



COMMERCIAL AGREEMENTS

Drafting, analyzing and revising contracts that involve specific elements of the industry. A well-written contract facilitates the relationship between parties and mitigates risks, thus avoiding future problems for the company.



COMPLEXITY

We provide assistance on agreements of all levels of complexity, from simple everyday demands to projects involving innovative or highly-regulated sectors, always ensuring consistency with the same due care and straightforwardness.



NEGOTIATIONS

Participation in negotiations and discussions regarding potential new deals and contracts, as well as ongoing contracts.



NEW PROJECTS

Constant analysis of innovations and alternatives in the market landscape for projects and business opportunities that involve the life sciences and health care sector.



BENEFITS

Assessment of company practices related to granting of benefits to employees, payroll legal treatment, regulation of health care plans, among others.



CONSULTING

Consulting on topics related to health services, medical equipment, cultivars laws, seeds, among others.

HOW WE CAN HELP

**RULES AND METHODS**

Supporting companies in establishing rules and methods for applicable transfer costing and customs valuation.

**TAX AND CUSTOMS**

Consulting on direct taxes, indirect taxes, social security taxes and customs matters.

**AMENDMENTS OF RULES AND PROCEDURES**

Governmental relationships for the amendment of rules and proceedings.

**REVIEWS AND OPPORTUNITIES**

Review of operations and identification of tax opportunities.

**DOCUMENTATION**

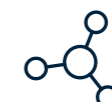
Obtaining permits, registrations and licenses.

**AUDITS**

Assisting on audits.

**TAX BENEFITS**

Obtaining tax benefits and special taxing systems.

**M&A AND DUE DILIGENCE**

Participation in the structuring of M&A operations, corporate restructuring and due diligence of tax matters.

**IMPORT TAXES**

Requests for amendments to taxes, particularly Import Taxes.

**DISPUTE RESOLUTION**

Administrative and judicial dispute resolution within the federal, state and municipal spheres.

**CERTIFICATION**

Obtaining good practices certificates (Authorized Economic Operators - OEA, for example).

PRIVACY, TECHNOLOGY AND CYBERSECURITY

HOW WE CAN HELP



TRAINING AND QUALIFICATION

Comprehensive or on-demand training and qualification on topics involving the Brazilian General Data Protection Law (LGPD), including: Data Protection Officer training; HR training; Overview training for the entire company; Privacy Committee training; training for clients and supplies, among others.



CYBER SECURITY

Support in contingency plans before the press, clients, authorities and titleholders, in addition to assistance in the risk assessment or identification of relevant damages to titleholders in the event of a security incident.



MARKETING

Legal consulting on marketing practices that involve personal data, the use of personal data in regulated sectors and the use of databases (big data).



PRIVACY BY DESIGN

Specific legal consulting on the development of products and services that involve the processing of personal data (privacy by design).



DOCUMENTS

Drafting and revising documents related to privacy, such as: privacy policies, impact reports, international data transfer agreements and data processing agreements, for example.



ARTIFICIAL INTELLIGENCE

Governance of algorithms and AI; Algorithmic audit and mapping of risks and impacts; Raising awareness on best practices and ethical conduct.



BRAZILIAN NATIONAL DATA PROTECTION AUTHORITY (ANPD)

Communication and representation before the ANPD.



MAPPING

Mapping of personal data flow, recommendations on legal bases and legal risks (gap analysis), and Legal Recommendation Reports.



INFORMATION SECURITY

Review of Information Security Policy and Incident Response Plan.

INTELLECTUAL PROPERTY, INNOVATION AND TECHNOLOGY

HOW WE CAN HELP



TRAINING

We provide our clients with specialized training on: techniques and strategies for intellectual property licensing, organization and management of intellectual Property portfolios, among others.



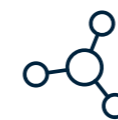
ASSISTANCE

We offer full assistance in monitoring administrative, civil and criminal law measures against infringement of intellectual property rights.



INNOVATION AND DISRUPTION

We assist our clients in proceedings involving innovation, creation and protection of disruptive initiatives.



M&A AND DUE DILIGENCE

Participation in the structuring of M&A operations and due diligence of intellectual property matters.



TAX MATTERS

We act in all tax-related matters concerning intellectual property and innovation.



CULTIVARS

We assist in the protection of cultivars before the Brazilian National Service for Plant Variety Protection (SNPC).



NEW TECHNOLOGIES

Digital Law, Internet of Things (IoT), Blockchain, Smart contracts; among others



COMMERCIAL AGREEMENTS

We draft and negotiate intellectual property agreements for intellectual property licensing and grant of rights, transfer of technology, provision of technical services, franchising, software, use of image, use of content licensing, technological co-branding cooperation, research and development, cultivars, among other various agreements involving intellectual property relationships.

ENVIRONMENTAL

HOW WE CAN HELP



LICENSING AND ENVIRONMENTAL PERMISSIONS

Identification of activities subject to licensing/permissions/grants in various economic sectors before the respective competent authorities, in addition to necessary documents and proceedings for such, including complex cases in contaminated or sensitive areas such as indigenous lands and environmentally protected lands (e.g. Conservation units), as well as other cases in various sectors, including agribusiness, chemical, among others.



BIODIVERSITY

Identification of opportunities and risks related to the use of biodiversity in products, including for verification of applicability and compliance with the regulations regarding access and shipment of genetic property and any associated knowledge or information.



SOLID WASTE AND REVERSE LOGISTICS

Assistance in developing a strategy to manage and allocate the appropriate disposal of waste, in order to comply with reverse policies for reverse logistics of products and packaging.



CONTAMINATED AREAS

Assistance in regulatory matters concerning environmental quality of real estate, particularly in the environmental management of contaminated areas (soil, ground water, body of water, etc.) before environmental authorities, control and oversight entities and in negotiating the allocation of environmental liability to third parties.



IDENTIFICATION

Gathering and analyzing regulations, restrictions and opportunities related to the use of specific chemical substances, including agrochemicals, among others, within the scope of the Ministry of the Environment (MMA), IBAMA, the Prosecution Office, and other relevant environmental authorities, including at a state and municipal level.



ENVIRONMENTAL AUDITS

We carry out environmental legal audits, in addition to assisting on the monitoring of internal audits of Environmental and Occupational Health and Safety matters.



FORESTRY MATTERS

We act on various fronts concerning forestry matters, particularly for verification and regulation of areas susceptible to exploitation or subject to special protection, identification of forestry-related liabilities within urban and rural area in collaboration with technical teams, establishing measures aimed at environmental regulation and assistance to obtain applicable permissions before the competent environmental entities.



ENVIRONMENTAL LIABILITY

Representation in judicial and extrajudicial litigation involving (i) strategic and institutional matters of high complexity that are related to the environment and have repercussions on the business's reputation and brand; and (ii) routine/operational matters of the business and its relationship with environmental control and oversight entities. We have extensive experience within different scopes of environmental liability (administrative, civil and criminal law), including the analysis of exposure of administrators and shareholders.

ESG

HOW WE CAN HELP

**STUDY ON GOOD PRACTICES**

Gathering information regarding good practices of each sector, within the ESG scope, considering the recommendations provided by international entities, in addition to legal assistance in benchmark analyses, in partnership with local and international technical consulting companies, thus encouraging the identification of best practices and ESG trends in different sectors and locations.

**DEVELOPMENT OF INTERNAL POLICIES AND POLICIES FOR RELATED PARTIES**

Development and review of internal policies and policies for related parties (contracted companies, supply chain), encompassing ESG, compliance, socio environmental and anti-corruption policies.

**SOCIAL ASPECTS**

Assessment of risks and opportunities related to social impacts identified for each sector (appropriate use of agrochemicals by rural workers, for example); Verification of measures and development of an action plan aimed at the inclusion of individuals in a situation of social vulnerability; Advising on administrative and legal proceedings related to social inclusion, harassment and abuse.

**SUSTAINABLE BUSINESS**

Assistance in the legal structuring of sustainable business, in the strategies for participation in the carbon credit market, and in the identification of opportunities through the obtainment or creation of sustainability seals.

**SUSTAINABILITY REPORTS**

Assessment of risks and opportunities in the publication of ESG and sustainability reports, and assistance in drafting reports in accordance with international standards and criteria, as well as assisting, when applicable, with demands from regulatory authorities and from the National Financial System, such as the Central Bank of Brazil (BACEN) and the Brazilian Securities and Exchange Commission (CVM). Assisting the drafting of Report on Social, Environmental and Climate Risks and Opportunities (GRSAC Report)

**RISK AND MATERIALITY ASSESSMENT**

Carrying out a materiality assessment of specific sectors and companies within the ESG scope, considering international standards (IFC, GRI, SASB, ODS, among others), in order to map important topics for our clients, as well as risks and opportunities related to ESG matters.

**ESG AUDITING**

Due diligence for evaluation of compliance from Audited Companies with ESG criteria (aligned with methodology established by the IFC, GRI, ODS, among others), and reporting of the existent structure. Through the audits, we also advise on the establishment of measures aimed at ESG integration, and the development, execution and monitoring of an action plan.

**ACQUAINTANCE WITH THE TOPIC**

Introduction and training on ESG, in order to contextualize and highlight the relevance of the topic, as well as identifying applicable opportunities and risks of each case.

CORPORATE/M&A

HOW WE CAN HELP

**CONSULTING AND OPINIONS**

Consulting and legal opinions/ memoranda on corporate elements and operations carried out in Brazil, including matters concerning governance and corporate structures that are more common for companies of the health sector.

**KNOWLEDGE**

Broad knowledge and monitoring of new opportunities involving the life sciences and healthcare sector, as well as developing a strong relationship with the main players of the sector.

**JOINT VENTURES**

We assist in agreements and negotiations of joint ventures or other forms of associations and strategic alliances between companies in the health sector, seeking to address the main concerns of the involved parties concerning governance, exclusivity, competition and financial return of the projects.

**OPERATIONS AND CONSULTING**

We advise on operations or consultations of all levels of complexity, from simple everyday demands to projects involving innovative or highly-regulated sectors, always ensuring consistency with due care and straightforward service.

**CORPORATE FOLLOW-UP**

Drafting everyday corporate documents, meeting the needs of companies in the sector.

**CORPORATE REORGANIZATION**

Planning and negotiating corporate reorganizations and analyzing the best structure to be implemented.

**MERGERS AND ACQUISITIONS**

Extensive experience in drafting documents and participating in the negotiations of M&A transactions involving one or more companies of the sector.

DEMAREST

demarest.com.br/en

