ANDERSEN

Newsletter

PHARMA & LIFE SCIENCES

February 2024

Andersen

Pharma & Life Sciences

| Newsletter | February 2024

Andersen in Spain

Risponsible for the Pharma & Life Sciences Area

Juan Ignacio Alonso
Andersen Partner
Corporate and M&A Law

In the first edition of Andersen Iberia's Pharma & Life Sciences Newsletter, we have collected the main news on legislation, compliance, labor, tax and industrial and intellectual property in the sector.

Aware of the importance that the Pharma & Lifesciences sector has in our economy, at Andersen Iberia we have formed a homogeneous group of top professionals who know the industry to perfection and who can cover all the needs of companies linked to this industry.

ANDERSEN.

SUMMARY

The substantive reform of EU pharmaceutical regulation

The reform builds on the existing stringent quality, safety and efficacy standards for the authorization of medicines and proposes new tools in several areas.

It is a well-known fact that some months ago (in 2023), **the European Commission published a press release announcing its proposal for a substantive reform of EU pharmaceutical regulation.**

The pharmaceutical industry is a key sector for the EU economy.

In 2020, EU companies invested more than €26.5 billion in research and development and are responsible for around 840,000 direct jobs. The EU, the UK and Switzerland represent the second largest investor in pharmaceuticals (€39.7 billion in 2020), after the US, which invested €63.5 billion in 2020 (EFPIA data).

When it comes to the manufacture of high-tech medicines, the EU is a clear world leader. Exports increased from €50 billion in 2002 to €235 billion in 2021, while imports rose from €32 billion to €100 billion in the same period. The EU trade surplus in medicines and pharmaceuticals reached €136 billion in 2021, the highest value on record (source Eurostat).

At the same time, **the EU is the second largest market for pharmaceuticals in the world.** According to the IQVIA MIDAS database, total pharmaceutical expenditure in the EU was around €230 billion in 2021, or 1.5% of the EU's GDP.

Given the importance of this industry in the European Union, **the European legislator considers that a "far-reaching" reform of European pharmaceutical regulations is necessary**, articulated through a proposal for a Commission Regulation amending Regulations 1394/2007 and 536/2014 and, therefore, repealing Regulations 726/2004, 141/2000 and 1901/2006, as well as a proposal for a European Commission Directive repealing Directives 2001/83/EC and 2009/35/EC.

The main objectives of this review according to the European Commission (the first major review since 2004):

1. Create a **single market for medicines** to ensure that all patients in the EU have **timely and equitable access to safe, effective and affordable medicines.**
2. Continue to provide an **attractive and innovation-friendly framework** for research, development and production of medicines in Europe.
3. **Drastically reduce the administrative burden** by speeding up procedures and significantly shortening authorisation times for medicines so that they take less time to reach patients.
4. **Improve availability and ensure** that medicines can always be supplied to patients, regardless of where they live in the EU.
5. Tackling **antimicrobial resistance (AMR)** and the presence of pharmaceuticals in the environment through the "One Health" concept.
6. Making medicines more **environmentally sustainable.**

But in what form will this reform take, what aspects will it affect, and what are the most innovative?

The reform builds **on the existing high quality, safety and efficacy standards for the authorisation of medicinal products and proposes new tools** in these areas:

- **Move from a single system of incentives for pharmaceutical companies to a modulated system of incentives that rewards companies that meet important public health objectives**, such as providing access to medicines in all Member States, developing medicines that address unmet medical needs, conducting comparative clinical trials, and developing medicines that can also treat other diseases. For medicines for rare diseases, a similar modulation for market exclusivity is proposed.

- **Make generic and biosimilar medicines more quickly available** and make public funding transparent.

- Addressing **drug shortages and ensuring security of supply.**

- **A modern and simplified regulatory framework with faster authorisations of new medicines.** For example, for evaluation, the EMA will have 180 days instead of 210 days. For authorisation, the Commission will have 46 days instead of 67 days. For the assessment of medicinal products of major public health interest, the EMA will only take 150 days for controlled areas of testing to support the development of innovative medicines, electronic submissions and electronic package leaflets.

- **Promoting innovation and competitiveness.**

- To achieve **greater environmental protection.**

- **Combating antimicrobial resistance** (AMR).

It goes without saying that the above shows the strong interest of the European legislator in promoting significant change in European pharmaceutical legislation (simplified procedures, early scientific advice from the EMA, controlled testing sites, minimum regulatory protection period of 8 years for companies marketing innovative medicines - including six years of data protection and two years of market protection -, standard duration of market exclusivity of nine years in the case of rare diseases, ensuring that the regulatory system can keep pace with scientific and technological progress by promoting innovative methods, creating a temporary emergency marketing authorisation for health crisis situations, simplifying the organisational structure of the European Medicines Agency ("**EMA**"), speeding up the marketing authorisation processes for medicinal products, environmental requirements for the authorisation of medicinal products, etc.), but without forgetting the need to adapt to digital advances and to the growing awareness of climate issues, which is currently in great demand.

Perhaps one of the most important aspects of the reform is the environmental awareness of the European pharmaceutical industry. According to the European Commission, scientific evidence shows that the improper manufacture, use and disposal of pharmaceuticals can have a negative impact on the environment. In addition, antimicrobials have been detected in wastewater treatment, as well as in effluent, surface and groundwater derived from production. In the view of the European Commission this is worrying as it leads to an increase in antimicrobial resistance. Endocrine disruptors are another important group of medicines that may pose a risk to the environment and public health.

In line with previous commitments made in the EU Strategic Approach on Pharmaceuticals in the Environment, **the reform will strengthen the environmental risk assessment of medicines to limit the potential adverse**

effects of medicines on the environment and public health. Environmental risk assessment is mandatory for all pharmaceutical companies placing their medicinal products on the EU market. **Marketing authorisation may be refused** if companies do not provide sufficient evidence that environmental risks have been assessed and that risk reduction measures have been taken, which is certainly innovative.

In any case, **this is a proposal for modification and renewal that will take time.** There are already some "voices" criticising some aspects of it. It is more than possible that **the approval of the reform will be delayed** not only because of its enormous complexity, but also because of the proximity of the elections to the European Parliament and the renewal of the college of Commissioners in 2024. We will be watching the situation closely. ■

Criminal liability of the legal entity in the pharmaceutical sector

The reform of the Criminal Code by Organic Law 5/2010 of 22nd June 2010 introduced the criminal liability of legal entities and outlined the characteristics of the system of organisation and management, as well as the monitoring and control measures that companies must take to prevent the commission of crimes within them.

By virtue of the provisions of Art. 31 bis of the Criminal Code, legal entities are criminally liable for those offences expressly provided for in the Code. This catalogue of offences has undergone constant reforms because of the enactment of various organic laws, such as Law 3/2023 of 28th March.

The following offences are currently included in this catalogue:

1. Illegal trafficking in human organs.
2. Against moral integrity.
3. Concealment of corpse
4. Trafficking in human beings.
5. Sexual harassment.
6. Prostitution, sexual exploitation and corruption of minors.
7. Discovery and disclosure of secrets and computer hacking.
8. Scam (I): common scams.
9. Scam (II): specific scams.
10. Swindling (III): improper swindling.
11. Frustration of implementation.
12. Punishable insolvencies.
13. Computer damage.
14. Intellectual and industrial property, market and consumer issues (I): intellectual property.
15. Intellectual and industrial property, market and consumer issues (II): industrial property.
- Shortages of raw materials or basic necessities.
- Misleading advertising.
- Fraudulent invoicing.
- Offence against free competition.
- Insider trading.
- Investor fraud.
- Corruption in business.

16. Intellectual and industrial property, market and consumer issues (III): disclosure of business secrets.
17. Intellectual and industrial property, market and consumer issues (IV): against consumer rights.
18. Intellectual property, market and consumer issues (V): against the market.
19. Intellectual and industrial property, market and consumer issues (VI): corruption in business.
20. Money laundering.
21. Illegal financing of political parties.
22. Against the Public Treasury and Social Security (I): tax fraud.
23. Against the Public Treasury and Social Security (II): against Social Security.
24. Against the Public Treasury and Social Security (III): subsidy fraud.
25. Failure to comply with accounting obligations.
26. Against the rights of foreign nationals.
27. Unauthorised development, construction and building.
28. Against natural resources and the environment.
29. Against animals.
30. Relating to ionising radiation.
31. Risks caused by explosives and other agents.
32. Against public health (I).
33. Against public health (II): drug trafficking.
34. Counterfeit currency.
35. Counterfeiting of credit and debit cards and travellers' cheques.
36. Bribery.
37. Influence peddling.
38. Embezzlement.
39. Hate and glorification.
40. Terrorist organisations and groups.
41. Terrorism.
42. Smuggling.

Through Article 129 PC, accessory consequences are established, which will be applied to the catalogue of previous crimes when they are committed within, with the collaboration of, through or by means of companies, organisations, groups or any other type of entities or groups of people who, because they lack legal personality, are not included in Article 31 bis, adding the following crimes to the previous ones:

1. Genetic manipulation.
2. Alteration of prices in public tenders and auctions.
3. Obstruction of inspection or supervisory activity.
4. Against workers' rights.
5. Counterfeit currency.
6. Unlawful association.
7. Criminal organisations and groups.
8. Terrorist organisations and groups.
9. Terrorism.

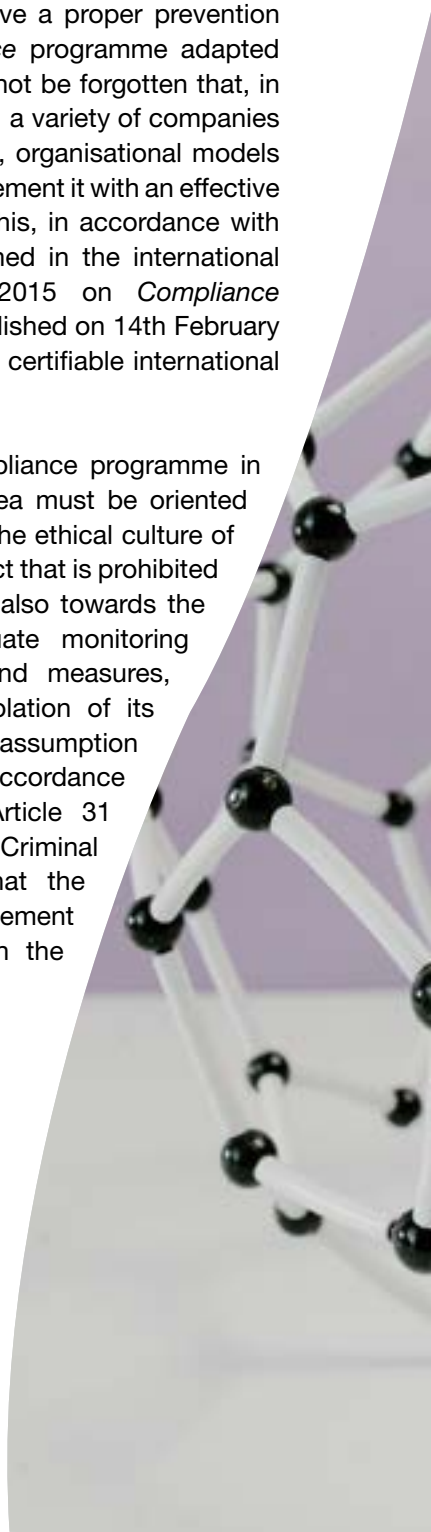
The fact is that the offences that can be committed by pharmaceutical or scientific legal entities are the same as those that can be committed by any legal entity, i.e. all the offences provided for in the *numerus clausus*. As they continue to be entities with legal personality, they are therefore exposed to all the legal risks inherent to their status. *All the more* so if we take into account that many of these companies have a truly powerful corporate structure in which de jure and de facto directors, various legal representatives, managers of different departments and a large number of employees coexist, moving within a market of goods and services and handling huge economic figures.

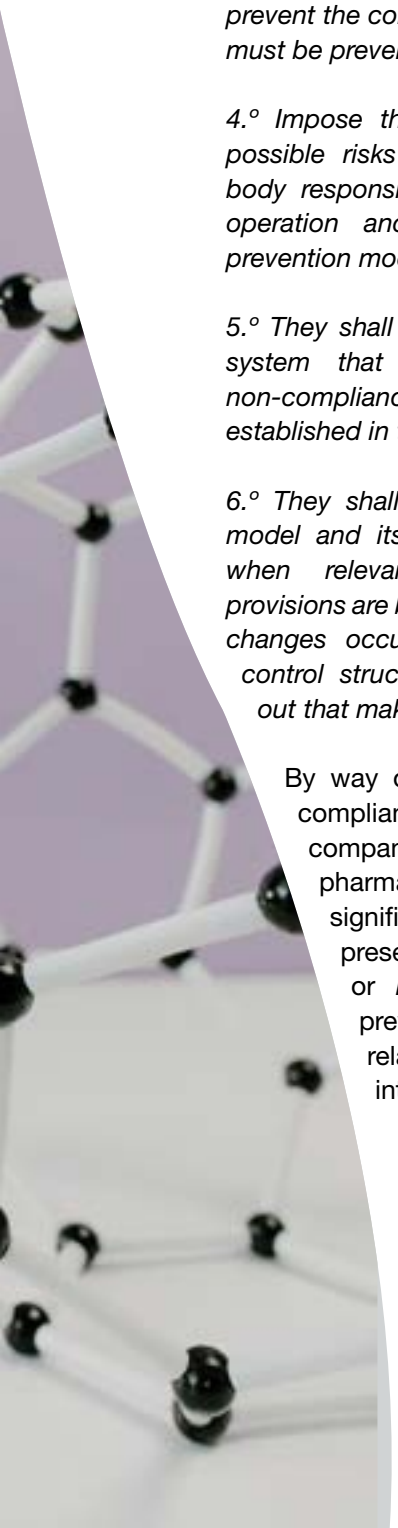
By virtue of art. 31 bis of the Penal Code, they would therefore be liable for the crimes that their legal representatives and administrators, de facto or de jure, commit in their name or on their behalf, which result in direct or indirect benefit for the entity. And, likewise, they would assume criminal liability for the offences committed by the workers, in the performance of their activities for the entity and on behalf of and for the direct or indirect benefit of the company, without the latter having established the necessary means of control over them.

Bearing in mind, therefore, that there is nothing to prevent these companies from committing any of the offences listed in the *numerus clausus*, it should be noted that in the specific context of the pharmaceutical and scientific industry there are some offences that are more likely to be committed by them, due to the nature and impact of their activity.

Prior to the analysis of the types that may present a greater risk of commission, it is extremely important to remember at this point that, in order to prevent the legal entity from being criminally liable, it is necessary for it to have a proper prevention plan, a specific *compliance* programme adapted to its activity (as it should not be forgotten that, in the breadth of this industry, a variety of companies coexist with different sizes, organisational models and policies), and to complement it with an effective internal procedure. All of this, in accordance with the first guidelines contained in the international standard ISO 196000: 2015 on *Compliance* Management Systems published on 14th February 2014, now replaced by the certifiable international standard ISO 37301: 2021.

Thus, any regulatory compliance programme in criminal matters in this area must be oriented not only towards defining the ethical culture of the company, or the conduct that is prohibited or permitted within it, but also towards the implementation of adequate monitoring and control processes and measures, precisely to avoid the violation of its principles and the possible assumption of future criminal liability, in accordance with the provisions of Article 31 bis, section 5, of our Criminal Code, which provides that the organisation and management models must comply with the following requirements:





"1.º They shall identify the activities in whose scope the offences to be prevented may be committed.

2.º They shall establish the protocols or procedures that specify the process for the formation of the legal entity's will, the adoption of decisions and the execution of the same in relation to them.

3.º They shall have appropriate financial resource management models to prevent the commission of crimes that must be prevented.

4.º Impose the obligation to report possible risks and breaches to the body responsible for overseeing the operation and observance of the prevention model.

5.º They shall establish a disciplinary system that adequately sanctions non-compliance with the measures established in the model.

6.º They shall periodically verify the model and its possible modification when relevant breaches of its provisions are brought to light, or when changes occur in the organisation, control structure or activity carried out that make them necessary."

By way of example, we can cite the compliance programmes of various companies within the health and pharmaceutical industry with a significant national and international presence, such as *Pfizer*, *Roche* or *Bayer*, which focus on the prevention of criminal conduct relating to aspects such as intellectual and industrial property, public health, the environment, business integrity, corruption or respect for privacy and the protection of personal data.

The compliance programmes are also fully compatible and respectful of the provisions of the various codes of ethics to which the different companies in the industry adhere. Among them, the Code of Good Practices of Farmaindustria or that of the Spanish Federation of Health Technology Companies undoubtedly stand out, both of which serve as a kind of guide for assessing the suitability and integrity of certain activities carried out by these companies. This is because these Codes go into detail in practically all areas of the industry's activities, defining prohibited and permitted conduct, developing common consultations and even including control bodies such as the Jurado de Autocontrol (Self-control Jury).

As we have had occasion to introduce, and given the nature of the pharmaceutical industry's operations and its involvement in the field of public health, it is particularly exposed to a series of crimes, including corruption between private individuals, influence peddling, fraud, tax offences, crimes against intellectual and industrial property, violation of privacy and computer hacking, computer damage, environmental crimes, crimes against social security and harassment at work.

It is important to underline the particular relevance and seriousness of crimes such as bribery and crimes against the integrity of the environment in the context of the pharmaceutical and scientific industry. These illegal acts, as they compromise ethics and integrity in commercial interactions and directly affect the environment, require greater attention and vigilance on the part of the authorities and the companies in the sector themselves, to prevent and sanction any conduct contrary to legality and business ethics.

Regarding **bribery** within the pharmaceutical industry, it is necessary to start from the idea that the criminal response will be given in the event that the granting of incentives, benefits or gifts of any kind goes beyond the limits of an administrative offence or a mere infringement of the Code of Good Practice of the Pharmaceutical Industry.

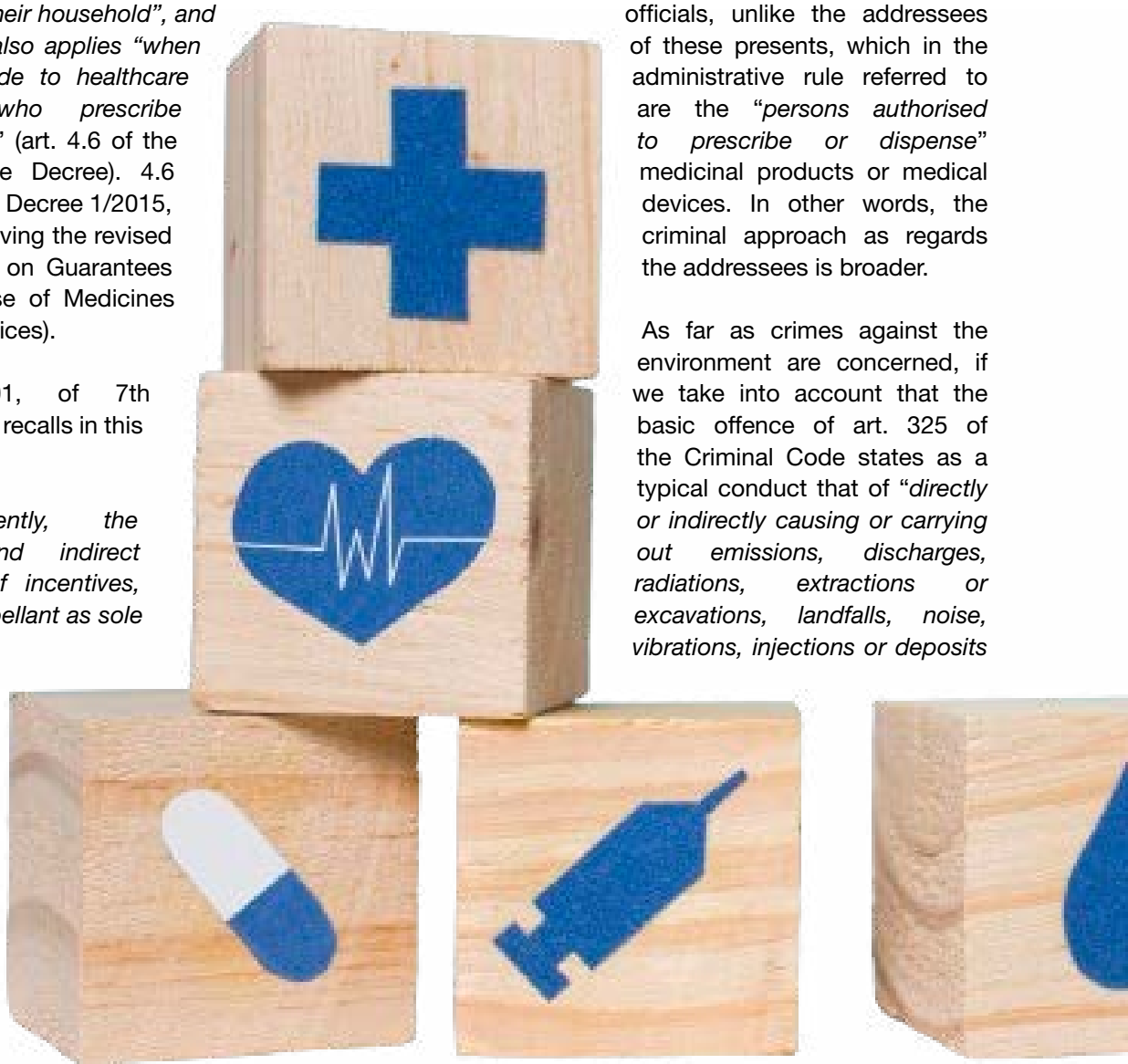
This can sometimes be somewhat complex because the truth is that, in this area, there is a total coexistence of criminal rules with administrative rules, which expressly regulate the prohibition of the granting of "*any type of incentive, bonus, discount, premium or gift, by anyone with direct or indirect interests in the production, manufacture and marketing of medicinal products, to health professionals involved in the cycle of prescribing, dispensing and administration of medicinal products or to their relatives and persons living with them", manufacture and marketing of medicinal products to healthcare professionals involved in the cycle of prescription, dispensing and administration of medicinal products or to their relatives and persons in their household", and this prohibition also applies "when the offer is made to healthcare professionals who prescribe medical devices*" (art. 4.6 of the Royal Legislative Decree). 4.6 Royal Legislative Decree 1/2015, of 24 July, approving the revised text of the Law on Guarantees and Rational Use of Medicines and Medical Devices).

STS 2052/2001, of 7th November 2001, recalls in this respect that:

> *"Consequently, the direct and indirect offering of incentives, by the appellant as sole administrator of a pharmaceutical laboratory, and therefore with a direct interest in the production, manufacture and marketing of medicines, to a doctor in charge of prescribing them, constitutes legally prohibited conduct. Conduct which, when carried out in relation to private professionals, gives rise to the administrative offence expressly provided for in Article 108 16 of the Medicines Act. But when the gifts or presents are offered or given to those who in the legal-criminal sense are public officials, that is to say, to health professionals integrated in the National Health Service, they constitute a crime of bribery, since in this case the principles of impartiality and objectivity that should govern the performance of public functions are additionally violated".*

It should be noted that the judgment refers to public officials, unlike the addressees of these presents, which in the administrative rule referred to are the "*persons authorised to prescribe or dispense*" medicinal products or medical devices. In other words, the criminal approach as regards the addressees is broader.

As far as crimes against the environment are concerned, if we take into account that the basic offence of art. 325 of the Criminal Code states as a typical conduct that of "*directly or indirectly causing or carrying out emissions, discharges, radiations, extractions or excavations, landfalls, noise, vibrations, injections or deposits*



in the atmosphere, soil, subsoil or land, underground or maritime waters, including the high seas, including transboundary areas, as well as water abstractions which, by themselves or jointly with others, cause or may cause substantial damage to the quality of the air, soil or water, or to animals or plants", It seems clear that any type of company is susceptible to carry out such an action, but this possibility is undoubtedly increased in the case of companies belonging to the pharmaceutical industry, precisely because their field of action involves the handling of certain chemical substances susceptible to generate all types of waste. Imagine, then, the discharge of wastewater from pharmaceutical manufacturing plants (which sometimes contain ingredients that are still active) or the improper disposal of unused medicines in landfills, with disregard for the regulations governing their removal and destruction.

It should also be borne in mind that this type of offence does not require the specific nature of the danger to the legal good, but rather the production of a state of risk verifiable *ex ante* (STS 141/2008, 8th April), a risk which, in addition, must be serious and likely to produce harmful consequences (for example, that there is a special intensity in the polluting act or that the damage is prolonged or reiterated over time, according to consolidated case law criteria such as that contained in rulings such as SSTS 81/2008, of 13 February or 916/2008, of 30th December).

Las sanciones pueden concretarse en multas que podrían oscilar hasta 25 millones euros, la disolución de la entidad o la inhabilitación para el ejercicio de actividades empresariales o profesionales por un plazo de hasta 10 años

For all these reasons and because of the growing importance of ecocides, it is important to conclude that proper prevention is necessary to avoid criminal prosecution of these conducts, which are punishable by prison sentences and/or substantial fines and which, ultimately, also jeopardise the reputational damage and the proper development of the industrial activity of the pharmaceutical company convicted. Likewise, it is important that the legislation be diligently adjusted to the context and the constant evolution of the pharmaceutical industry. Developments in this sector can have no other answer than a flexible and adaptive legislation that safeguards - both preventively and punitively - environmental integrity.

In conclusion, the criminal consequences that the legal entity could incur if found guilty are numerous. It could be sanctioned with the penalty foreseen for the offence in the specific case. These penalties can take the form of fines of up to €25 million, dissolution of the entity or disqualification from the exercise of business or professional activities for up to 10 years.
In addition, the legal entity could be subject to accessory consequences provided for by law, such as the prohibition to obtain public subsidies for up to 10 years, the prohibition to contract with public administrations for up to 10 years or the publication of a conviction in the Official State Gazette.

And all this without forgetting that their guilt undoubtedly entails a loss of their corporate image versus reputational damage, in which the violation of their corporate social responsibility becomes evident. In other words, a powerful message would be sent to society, suppliers, consumers and different operators in the legal and commercial traffic that the specific guilty entity would not be preventing the commission of crimes within it, which would also mean a loss of confidence and, ultimately, a loss of income, as some of the penalties envisaged in art. 33.7 of the Criminal Code are the suspension of its activities, the closure of its establishments, disqualification from obtaining subsidies or financing mechanisms and, in the worst case, the dissolution of the legal entity.

Review of obligations to be fulfilled by companies in 2024

1 Quota for the reservation of jobs for people with disabilities

All companies that reach the threshold of 50 workers are obliged to employ at least 2% of workers with disabilities (art. 42 of Royal Legislative Decree 1/2013 of 29 November).

2 Equality plan and pay audit

As of the entry into force of Royal Decree-Law 6/2019, companies with more than fifty employees are obliged to draw up and implement an equality plan (article 45.2. Organic Law 3/2007, of 22nd March, for the effective equality of women and men). Therefore, as of March 2022, companies with more than fifty employees are obliged to have an equality plan in place, which must be registered with REGCON.

3 Annual remuneration record

The obligation to keep an annual pay register is provided for in Article 28.2 of the Workers' Statute and applies to all companies, irrespective of the number of employees.

Companies that do not comply with this obligation are liable to fines of between 751 and 7,500 euros (Art. 7.13 and 40.1b) TRLISOS).

Important Note: In cases where no agreement is reached, both regarding the equality plans and the different protocols, being a legal obligation, they can be closed and applied without agreement, if it is accredited that the negotiation has been carried out.

4 Workplace Harassment Protocol

Following the entry into force of Organic Law 3/2007, companies are obliged to implement an action protocol to deal with workplace, sexual and gender-based harassment, which includes specific procedures to prevent and act against it.

This obligation applies to all companies, regardless of their size, and has been reinforced by the entry into force of Organic Law 10/2022 of 6th September.

Although the protocol is mandatory for all companies, companies with more than 50 employees must have an Equality Plan, so the process of implementing the harassment protocol is carried out as part of the negotiation of the equality plan.

Companies that do not comply with this obligation may be fined between 751 and 7,500 euros (Art. 7.13 and 40.1b) TRLISOS) and if it is considered a very serious offence, the penalties may range from 7,501 to 225,018 euros.

5 Digital disconnection protocol

The right to digital disconnection is set out in art. 88 of Organic Law 3/2018 on the Protection of Personal Data and Guarantee of Digital Rights, which establishes the duty of all companies, regardless of their size, to have an internal policy and a mandatory internal procedure to guarantee the right to digital disconnection and preserve the rest time of workers, once the working day is over.

6 Internal reporting channel for reporting criminal and/or unethical behaviour

As of 31st December 2023, the whistleblower channel will be mandatory in companies with more than 50 employees because of Law 2/2023 of 20th February, regulating the protection of persons who report regulatory infringements and the fight against corruption.

7 LGTBI protocol to avoid discrimination in the company

On 2nd March 2024, the obligation for companies with more than 50 employees to have a specific protocol to prevent discrimination against workers in this group, to be negotiated with workers' representatives, comes into force.

The need to review the implementation of technologies for the use of biometric data for time and attendance or access control

On 27 November 2023, the AEPD published a guide on the processing of time and attendance control using biometric systems, which puts the use of these technological tools at risk.

Article 4(14) of the GDPR defines biometric data as "personal data obtained from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person which allow or confirm the unique identification of that person, such as facial images or dactyloscopic data". According to this definition, biometric data are all data that allow the identification or authentication of a person.

Companies that use this type of technology to comply, for example, with the registration of the working day or for access control for both work and non-work purposes, should review their use, given that the AEPD has modified the interpretation on the typology of data that it gave to biometric data in which, in accordance with the guide published by the AEPD on the processing of personal data in labour relations, dated 18 May 2021, it considered that the processing of biometric data in cases of one-to-one identification are not special categories of data, in which case they may be used for compliance with a legal obligation or for the performance of a contract.

Based on the Guidelines published by the European Data Protection Board on 26 April 2023, the AEPD has revised its interpretation because,according to these Guidelines, both biometric identification and biometric authentication are processes that involve the processing of special categories of data.
This means that the established criteria are reinforced, and organisations will have to review the impact assessment, which was carried out at the time, in order to prove that the use of these tools passes the suitability, necessity and proportionality of the processing and the technical, organisational and legal measures implemented until now will have to be reviewed in order to be reinforced.

The AEPD classifies the use of biometric data as an independent "High Risk" data processing as it considers that these are special categories of data in accordance with article 9.1 of theGDPR, which as a general rule establishes the prohibition of the processing of special categories of data, unless we are dealing with one of the cases envisaged in number 2 of the aforementioned article 9.

In the case of time recording and access control for employment purposes, in order to overcome the lifting of the prohibition provided for in Article 9.1, we could consider the provisions of letter b) of number 2 of Article

9 to be applicable, which expressly states:

> *"b) processing is necessary for the purposes of the performance of obligations and the exercise of specific rights of the controller or of the data subject in the field of employment law, social security and social protection, in so far as authorised by Union law of the Member States or by a collective agreement under the law of the Member States providing for appropriate safeguards for the respect of the fundamental rights and interests of the data subject"*

The lifting of the prohibition could therefore be applied on the basis of the fulfilment of a legal obligation of the controller in the field of employment, safety and social protection, insofar as this is authorised by a rule having the force of law, whether laid down by the European Union or by the law of one of the Member States, or by a collective agreement, provided that measures are taken which respect the fundamental rights and interests of the data subject.

The applicable legislation would be RDL 8/2019, of 8 March, article 10 of which regulates the obligation to record the working day as a way of combating precarious employment and establishes the modification of article 34 of the Workers' Statute, adding a new section 9 which reads:

> *"…The company shall guarantee the daily record of the working day, which must include the specific start and end times of the working day of each worker, without prejudice to the flexible working hours established in this article. By means of collective bargaining or company agreement or, failing this, by decision of the employer after consultation with the legal representatives of the workers in the company, this attendance register shall be organised and documented. The company shall keep the records referred to in this provision for four years and they shall remain at the disposal of the workers, their legal representatives and the Labour and Social Security Inspectorate."*

For the AEPD, this legal obligation to implement a working time register does not legitimise or protect the processing of biometric data, given that the regulation does not refer to the use of biometric data to keep the working time register and, since the data in question belong to special categories of data, it is necessary for it to be established in a legal regulation.

In relation to access control for work purposes it is article 20.3 of Royal Legislative Decree 2/2015, of 23 October, approving the Revised Text of the Workers' Statute Law, which states that:

> *"3. The employer may adopt the measures it deems most appropriate for monitoring and control to verify compliance by the worker with their work obligations and duties, keeping in their adoption and application the consideration due to their dignity and taking into account, where appropriate, the actual capacity of workers with disabilities".*

However, as in the previous case, this article does not mention the use of biometric data to establish access control.

This interpretation is also included in Opinion 1/2023 issued by the Transparency and Data Protection Council regarding the processing of biometric data through the use of facial recognition and/or fingerprint devices for the time control of City Council staff, in which it states that Spanish legislation does not contain any specific authorisation to consider the processing of biometric data necessary for the purpose of time control or access control for employment purposes.

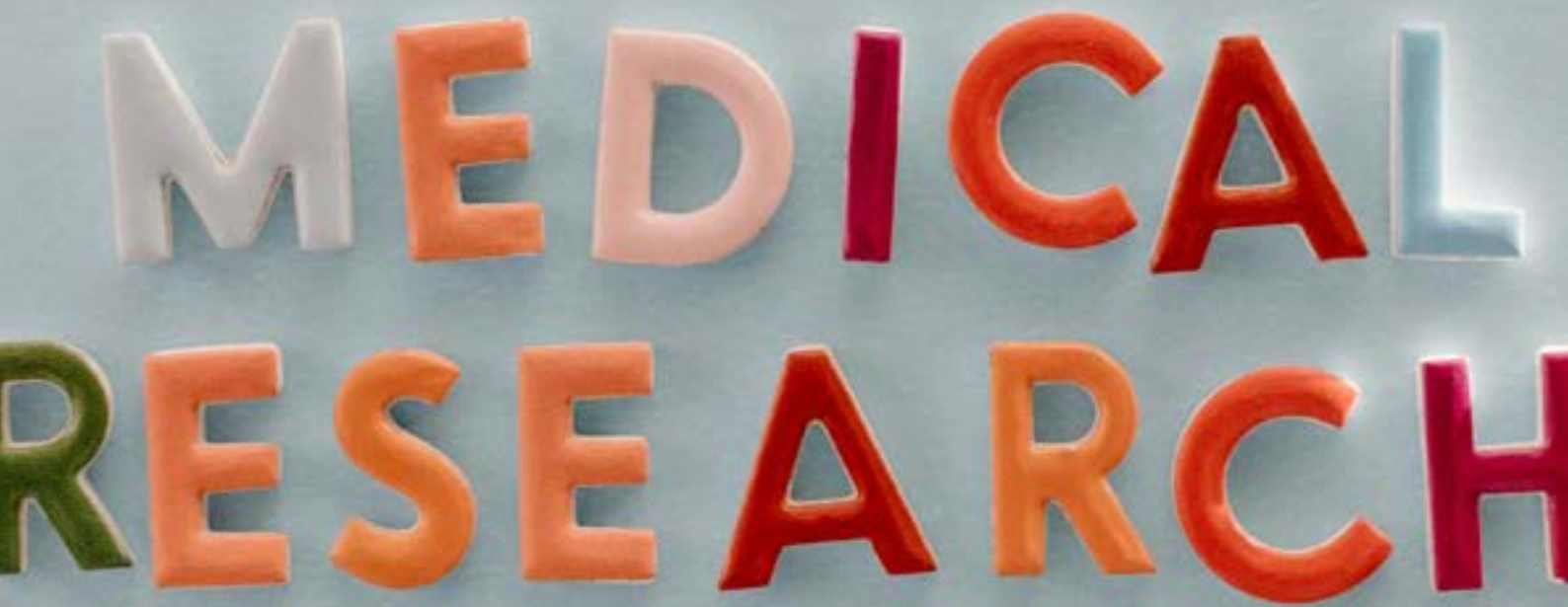
Based on this, we can conclude that organisations should review the criteria based on which they decided to implement this type of tool on the basis of the following points:

1. Analyse the implementation criteria in order to ensure that they pass the adequacy, necessity and proportionality data protection test.

2. Identify that there is a circumstance for lifting the prohibition on processing special categories of data and a condition that legitimises the processing, which cannot be based on consent.

3. Any use of biometric data must have its own circumstance for lifting the prohibition on processing.

4. Once the Data Protection Judgment has been passed, organisational, technical and legal safeguards must be implemented, and a risk analysis carried out. ■



Parallel imports of medicines: repackaged or relabelled?

The European Community (now the European Union) was originally based on three basic freedoms: free movement of people, capital and goods. The different economies of the EU states mean that importing medicines - after the first marketing - from one state to another is a business. As a principle, the trademark right is *exhausted* with the first marketing of the product in the European Economic Area (EEA) by the owner or with his consent. The exhaustion theory seeks to reconcile the freedom of movement of goods and the exclusive right that the trademark consists of. Hence, national exhaustion (but not in the EU) historically turned into Community exhaustion with the first lawful marketing in an EU state (after the EEA).

Thus, *only* when there are *legitimate* reasons, and particularly when "*the condition of the goods has been altered or changed after they have been put on the market*" (Art. 15(2) EUTR and Art. 36(2) TM), *would trademark rights be revived*, even against the free movement of goods. In such a case, the (*undermined*) functions of the trademark would take precedence over the freedom of intra-Community movement and, consequently, the exercise of trademark rights would no longer constitute a measure having an effect equivalent to the restriction of trade between Member States.

However, parallel importation of the medicinal product "as it was" lawfully acquired at the time of the first purchase is not possible either, since health legislation, to protect the health of citizens, requires certain *intelligible* information on the products. This is why a package leaflet and other information in the language of the importing country is required. This implies the need to handle the product, probably opening it to replace the leaflet in the other language, or the inclusion of certain information on the outside of the packaging, including the holder's own brand name.

There are therefore two actions that can be taken to this effect in relation to the original products: repackaging and relabelling. The former is more incisive, as it involves the insertion of the manufacturer's mark again (by the parallel importer), while the latter involves a milder treatment.

The CJEU, in a body of doctrine known as "*Bristol Myers*", laid down the conditions to be met by the parallel importer to repackage without infringing trademark rights (inter alia, cases C-427/93, C-429/93, C-436/93 and C-379/97). Basically, these conditions were as follows:

- Prove that the exercise of the trademark artificially partitions the markets between member states; which is the case when repackaging is objectively necessary to market in the state of importation.
- No alteration of the product.
- Warning of repackaging with identification of the person responsible for repackaging and the manufacturer.
- Prior notification to the trademark owner with sample of repackaging (if required).
- Repackaging must not be detrimental to the reputation of the holder.

Thus, the Falsified Medicines Directive 2011/62 and Commission Regulation 2016/161 imposed two security measures to further protect the health of citizens: Firstly, a unique identifier to guarantee the authenticity of the product (barcode); and secondly, a tamper-evident device (sealing with

adhesive tape or similar). The barcode guarantees that the medicinal product comes from its legitimate manufacturer; the integrity of the seal (adhesive tape) guarantees the authenticity of the contents. All persons involved in the supply chain of the medicinal product, from the manufacturer to the retailer, should verify both security systems.

In this context, the judgments of the CJEU of 17th November 2022 (cases C-147/20, C-204/20 and C-224/20) have arisen, where importers consider repackaging to be necessary (as the closure has been corrupted to introduce the new leaflet), and manufacturers consider that a new closure can be added, without repackaging.

From the outset, the CJEU admits both relabelling and repackaging, although the latter will only be possible when the closure cannot be objectively replaced by an equivalent closure (it is not sufficient that traces of opening remain to resort to repackaging). Repackaging will also be objectively necessary where the import market (or a significant proportion of it) has a resistance to relabelled medicinal products which means that effective access to that market is hindered.

El TJUE admite tanto el reetiquetado como el reenvasado, si bien este último, solo será posible cuando el cierre no pueda ser objetivamente sustituido por un cierre equivalente

In such cases where repackaging is necessary, the manufacturer may not enforce his trademark rights, as this is regarded as a measure equivalent to partitioning off the markets of the Member States. Conversely, he may oppose it, even if the trademark on the outer packaging is replaced by a different trademark (but not on the inner packaging of the product). It may also be opposed if the insertion or omission damages the reputation of the trademark.

These rulings seem to restrict the possibility of repackaging medicines in parallel trade, leaving it restricted to very special cases in which - in addition - the burden of proof of the objective necessity of repackaging will be on the parallel importer. ■

The creation of the European Health Data Space as a driver of innovation

The proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space ("**EEDS**") of 3rd May 2022 is likely to come into force before the European elections next June 2024, following the agreement reached by the European Parliament on 13thDecember 2023 and the preparatory work adopted by the European Council at its meeting on 12th January 2024

The creation of the EEDS is part of the European Data Strategy (which proposes the creation of common European data spaces in specific areas). It aims to facilitate the exchange of health data between Member States to improve cross-border healthcare, while ensuring the protection of privacy and information security.

It also aims to introduce secure tools for the exchange and re-use of health data to create opportunities for research and innovation, such as reducing the costs of data acquisition, integration and processing, or shortening the time to market for new products and services in a secure environment that safeguards the rights of European citizens.

The EEDS must coexist with other cross-cutting legislation such as the General Data Protection Regulation (EU), the Data Governance Regulation, the Data Law Regulation, the future Artificial Intelligence Regulation and the NIS Directive, as well as with sector-specific legislation such as the Medical Devices Regulation (EU), the In Vitro Diagnostic Medical Devices Regulation (EU), as well as the Cross Border Healthcare Directive.

While the Directive on cross-border healthcare was a first step towards facilitating cross-border exchange of electronic health data, it has not proved sufficient either in its voluntary nature or in its scope (very limited to primary use of data) to create a true common health data space.

The main new features introduced by the EEDS are as follows:

Establece estándares comunes para la interoperabilidad de los sistemas de información de salud en los Estados Miembros.

It establishes common standards for the interoperability of health information systems in the Member States. 1

It facilitates access to and exchange of health data between Member States, enabling more effective health care for citizens moving or receiving treatment abroad. 2

It ensures high standards of security and privacy for health information, implementing concrete measures to protect sensitive data and ensure compliance with data protection regulations. 3

It seeks to stimulate operators' research and development within the single European framework, by allowing wider access to health datasets, under strict privacy and ethical controls. 4

It introduces mechanisms for citizens to participate in the management of their own health data, promoting transparency and control over personal information. 5

Regarding improvements introduced to foster innovation and knowledge, the EEDS harmonises and regulates across the EU some secondary uses of health data under certain conditions:

1 Scientific research: The use of health data for scientific research purposes is allowed, provided that strict ethical and privacy standards are met. In addition, the importance of ensuring anonymisation of data where possible is emphasised.

2 Health statistics: Health data can be used to produce health statistics, thus contributing to health policy planning and evaluation, provided that privacy and security standards are respected.

3 Development of health products and services: The use of health data is allowed for the development and improvement of health products and services with the aim of driving innovation and quality of care.

The central platform for the secondary use of electronic health data will be DatosSalud@EU (HealthData@EU) and the central mediator and platform for the patient's digital health: MyHealth@EU (MyHealth@EU).

In short, with the EEDS, public and private operators, regulators and researchers in the health, pharmaceutical and medical devices sectors, among others, will have the opportunity to access a common European health data space of unparalleled size in the international arena, which will also enjoy all the guarantees and security for patients.

A proper and effective use of this EEDS together with current artificial intelligence tools could mean an unstoppable advance for health and R&D&I activity in favour of more accurate diagnoses, personalised and rapid treatments, lower costs and treatments, increased innovation and the creation of a true single market for healthcare products and services for the ultimate benefit of public health and patients. ■

VAT on the transfer of vehicles to employees

The taxation of the transfer of vehicles to employees has traditionally been - and still is - the subject of many controversies with the tax inspectorate, due to its different implications in the field of Value Added Tax (VAT) and Personal Income Tax.

In the context of VAT, several relevant judicial and administrative rulings have recently been issued, which have had an impact on the taxation of the transfer of vehicles to employees for their private use since the Court of Justice of the European Union (CJEU) answered the question referred for a preliminary ruling on the interpretation of Article 56 (2) of Directive 2006/112/EC of 28th November 2006 on the common system of value added tax on the VAT liability of the transfer of vehicles to employees.

1 THE JURISPRUDENCE OF THE CJEU AND ITS IMPACT ON THE MATTER

The judgment on that question concludes by clarifying that the first subparagraph of Article 56(2) of Council Directive 2006/112/EC of 28th November 2006 on the common system of value added tax, as amended by Council Directive 2008/8/EC of 12th February 2008, is interpreted as meaning that the supply by a taxable person of a business vehicle to an employee does not fall within its scope if the transaction cannot be classified as a supply of services for consideration within the meaning of Article 2(1)(c) of that directive. On the other hand, if the transaction falls within the scope of the first subparagraph of Article 56(2) and is a supply of services for consideration within the meaning of Article 2(1)(c), the employee is granted the permanent right to use the vehicle for personal use and to keep other persons away from the vehicle in return for remuneration and an agreement period of more than 30 days.

The Central Economic Administrative Court (TEAC) modified its interpretation on the application of VAT to the transfer of vehicles by a company to its employees in its resolution 3161/2019 of 22nd February 2022. It established that such a transfer constitutes a supply of services subject to VAT when it involves a consideration assessable in cash for the employer, such as the payment of a rent by the employee, the waiver of part of his or her salary in cash, or if it is established that part of the work performed has an economic value associated with the transfer of the vehicle. In the context of an employment relationship, it cannot be automatically presumed that the transfer of the vehicle does not constitute a valuable consideration, as the use of the vehicle can be understood as implying a financial consideration from the employee to the employer.

2 THE PROVISION OF SERVICES AND WHETHER THEY ARE PAID FOR OR FREE OF CHARGE

It has already been established by the CJEU in its judgment of 29th July 2010 Astra Zeneca UK Ltd, C-40/09, that the concept of "*provision of services for consideration*" implies, in any case, the presence of a direct connection between the service offered and the compensation received.

However, the provision of services for consideration within the meaning of Article 2(1)(c) of Directive 2006/112 shall only be the provision of services for consideration where:

- The worker may be subject to a fee for the use of the vehicle provided by the company.
- The employee may waive part of his or her salary to cover the costs associated with the use of the vehicle.

- The employee can choose between several options offered by the company, where the use of the vehicle is conditional on the waiver of other benefits.

The Directorate General of Taxes (DGT) reiterates, in its Binding Consultation V0593-23, that the same considerations have been taken up later in the resolution of the TEAC, 3161/2019 of 22nd February 2022. It then concludes that, based on the rulings, "*it can be concluded that in those cases in which there is a direct relationship between the service provided by the employer (remuneration in kind) and the consideration received by the employer (the employee's personal work), there is a provision of services for consideration for value added tax purposes*".

Therefore, as confirmed by the Court of Justice of the European Union in its judgment of 20th January 2021, a supply of services involving the use of business assets for the personal purposes of the taxable person or his staff, or generally for non-business purposes, cannot be equated to a supply of services for consideration within the meaning of Article 26(1)(a) of Directive 2006/112. This is because the goods in question did not give rise to a right to deduct input VAT, as required by that provision. Therefore, it cannot, in the alternative, be regarded as a supply of services based on Article 26(1)(b) of the same directive, without undermining the useful effect of the input tax deduction requirement laid down by the first provision mentioned.

3 THE RIGHT TO DEDUCT.

Binding consultation V0593-23 continues by ruling on the relevant deductions that may be applied in the case of being effectively subject to VAT and not exempt, clarifying that the transfer of vehicles to managers will be understood as a transaction not subject to VAT as long as the availability of the vehicles for personal use is treated as a service to employees, which does not give rise to the right to deduct the tax paid by the consultant. In this scenario, the amounts paid for the acquisition of these vehicles cannot be deducted to any extent.
Finally, it was determined in this consultation that the deduction of input VAT on the purchase of vehicles will depend on their use for business or professional activity, in accordance with the provisions of Law 37/1992 of 28th December 1992 on Value Added Tax (LIVA).

4 NOTE FROM THE TAX AGENCY

In order to try to "close the circle", the State Tax Administration Agency (AEAT) issued an informative note in September 2023 which sets out the interpretative criteria which, in its opinion, should govern the taxation of the transfer of vehicles from companies to their employees in the field of VAT (and Personal Income Tax), for the part of the private use that the latter make of them.

According to the tax authorities, the transfer of a vehicle to an employee will constitute an onerous supply for VAT purposes where '*the employee pays an income to the employer for the transfer of the vehicle, whether in money, benefit or economically valuable waiver of rights*'.

Regarding the deductibility of the VAT paid on the purchase of vehicles transferred to employees, it understands that this is conditional on the vehicle being used for an activity subject to VAT, considering the actual degree of use which, in practice, may be higher or lower than the 50% established as a presumption in the LIVA.

Thus, in application of the criteria on onerousness and allocation for the case of mixed-use vehicles, the AEAT concludes that the vehicle transferred to the worker will be fully allocated to the economic activity if the part not intended for work use is transferred for consideration, and VAT at the general rate (21%) will accrue on this part. On the other hand, if the transfer for private use is made free of charge, the asset will be partially assigned, and the deduction of input VAT will depend on the percentage of use for business purposes, thus excluding the percentage corresponding to the free transfer of the vehicle to the employee.

Finally, in line with the conclusions reproduced above, the AEAT note points out that, in those cases in which the employer has deducted input VAT on the acquisition of the vehicle and, subsequently, has transferred the vehicle free of charge to the employee, there will be a supply of services classified as self-consumption subject to VAT (for the private use part). Otherwise, if the company

had not deducted the input VAT on the purchase of the vehicle and subsequently transferred the vehicle free of charge to the employee, this would be a self-consumption not subject to VAT.

5 THE DETERMINATION OF THE TAX BASE

To determine the taxable amount of VAT (if VAT has to be settled or charged), the AEAT's information note distinguishes between two scenarios, namely the following:

- In the case of a transfer in which there is no onerous nature, there will be no transaction for VAT purposes (unless it is a case of self-consumption of services).

- In the case of a transfer for consideration, this is a transaction subject to VAT. In this case, the taxable amount of the supply of services must be determined based on the percentage of availability of the vehicle for private purposes, and the special rule for determining the taxable amount for related-party transactions applies, insofar as there is a link between the company and the employee.

6 CONCLUSIÓN

Undoubtedly, this new compendium of rulings and decisions has reviewed and clarified some of the most controversial issues in the indirect taxation associated with the transfer of vehicles to employees, although we fear that there will continue to be conflicting interpretations between taxpayers and tax administrations, given the subjectivity of some aspects linked to the practical application of the current regulations.

In practice, there are many companies that lend vehicles to their employees to provide them with a work tool suited to the needs of the sector, finding a sticking point in the definition of their remuneration policy and, as if that were not enough, in their relations with the tax office.

Consequently, it will be necessary to confirm whether the tax treatment applied to the transfer of vehicles is in line with the doctrine, without losing sight of the possibility of new rulings on the matter, as the ones we have seen in recent years will most likely not be the last.

In this sense, for example, the Supreme Court has just pointed out, in its Judgment 538/2024 (Rec. 5226/2022) of 29th January 2024, that the transfer of a vehicle used for business purposes to an employee for his private use, free of charge, where the employee does not make any payment or cease to receive any part of his remuneration as consideration and the right to use the vehicle is not linked to the waiver of other benefits, is not subject to VAT, even if part of the input VAT has been deducted for the vehicle. ■

Next event Andersen

‘European Health Data Space.
Its impact on E-Health and data reuse’.

The proposed regulation for the creation of the European Health Data Space is immersed in the European Data Economy Strategy and must coexist, among others, with cross-cutting regulations such as the General Data Protection Regulation, the Data Governance Regulation, the Data Law Regulation and the future Regulation on Artificial Intelligence.

Andersen organizes, together with Farmaindustria and Diater Laboratorios, a conference in the Madrid office to explain the keys to the European Health Data Space.

Register

See more

29 february 2024

Pharma & Life Sciences

| Newsletter | February 2024

Andersen in Spain

Risponsible for the Pharma & Life Sciences Area

Juan Ignacio Alonso
Andersen Partner
Corporate Law

Victoria Caldevilla
Labor and Employment Law Partner

María Suárez
Privacy & Intellectual Property Partner

José Garrido
Privacy & Intellectual Property Partner

María Victoria Vega
Litigation Partner

Isabel Martinez
Privacy, IT & Digital Business EU & Competition Law Partner

Esmeralda Iranzo
Compliance Director

Jesús Alemany
Tax Director

CONTACT

ANDERSEN.

February 2024
Newsletter Pharma &
Life Sciences