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Life Sciences 2024

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Portugal: Trends & Developments

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Trends and Developments

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Sérvulo & Associados is a Portuguese full-service law firm with 25 years of operation. It has a highly competent multidisciplinary team of more than 100 lawyers who are trusted by a vast number of private and public entities, both domestic and international, in the Portuguese-speaking legal markets and in all the most significant economic sectors. The life sciences team has in-depth knowledge of the life cycles of drugs, medical devices and other health products, enabling it to provide specialised advice at all stages, including research and development of new products and their respective intellectual property issues, data protection, regulation and inherent litigation.

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Life Sciences in Portugal: An Introduction

Overview

The technology and life sciences sector is experiencing rapid growth and evolution in Portugal due to advancements in research, regulatory policies and the integration of innovative technologies.

Portugal is a significant player in clinical trials and has attracted substantial investments from pharmaceutical companies, resulting in economic development. The government has taken steps to enhance the capacity and autonomy of Clinical Research Centres, and the compliance with the EU Regulation on Clinical Trials is transforming the landscape of clinical research practices.

Pioneering institutions like the Institute for Medical Systems Biology and the Católica Biomedical Research Centre are driving innovation in biomedical and digital technologies in Portugal.

Healthcare delivery in Portugal is undergoing a revolution with the adoption of cloud-based technologies and artificial intelligence (AI). From digital symptom evaluators to AI-powered dermatological diagnoses, technology is enhancing efficiency, accuracy and accessibility in healthcare services.

The integration of the Unified Patent Court (UPC) and the implementation of the SPC Waiver Regulation are causing significant changes in intellectual property litigation in the life sciences sector.

Life Sciences and Technology

Research and investigation

The biomedical investigation industry has been growing rapidly and has attracted significant public and private investments, envisioning the prosperity and developments in the life sciences sector.

In line with this vision, the Institute for Medical Systems Biology (NIMSB) was developed in 2023 by Nova University of Lisbon, in partnership with the Max Delbrück Centre in Berlin. It presents itself as a new centre of excellence that aims to apply emerging biomedical and digital technologies and innovative health solutions, focusing on the understanding of human biology and physiopathology on a cellular and molecular level.

Moreover, in late 2023, the Faculty of Medicine of the Portuguese Catholic University opened a new research centre, the Católica Biomedical Research Centre, the main objective of which is to promote health through fundamental science. The centre is staffed by talented researchers who utilise innovative technologies to unify medicine, biology and engineering. They aim to understand complex systems and develop solutions to current and future social challenges related not only to human health but also to the planet's well-being.

The government has recently created a programme called *Saúde+Ciência* (Health+Science) to boost scientific research in the field of healthcare. The aim of the programme is to encourage research in public institutions that offer health services and care, to train and appreciate health professionals, and to enhance the implementation of health promotion and disease prevention activities. Thus, the goal is to improve the organisation and quality of healthcare and services.

Focusing on projects targeted at specific therapeutics, the Champalimaud Foundation has recently received funding to invest in clinical research for pancreatic cancer.

The use of AI in the health sector

The healthcare industry has been undergoing a significant transformation due to technological advancements, particularly in AI. These advancements address various issues, including escalating costs, limited access to healthcare and disparities in healthcare delivery. AI's capacity to process large datasets and emulate human cognitive abilities has resulted in the creation of autonomous systems, reshaping healthcare models fundamentally.

Artificial intelligence is on the path to becoming consensually recognised by the scientific and clinical communities as a tool that can help increase accuracy and avoid delays in treatment, potentially saving lives when it comes to preventing the development of diseases and diagnosing pathologies.

Examples of how technology is being used in healthcare in Portugal include the following.

- A digital symptom evaluator available on the CUF (a private Portuguese hospital) mobile app allows patients to answer a series of questions in order to receive a possible diagnosis or referral, serving as a preliminary assessment.
- In early 2024, the National Health Service (NHS) introduced a funding line for the implementation of AI tools in dermatological diagnoses. Given the difficulty of accessing answers in this area, the NHS believes that the adoption of AI tools, which are duly validated and supervised by dermatologists, can provide faster and more accurate diagnoses for NHS users. Through an app, individuals can take a picture of their skin condition and, if necessary, it will be sent to a dermatologist with high priority, reducing the demand for face-to-face consultations.
- The NHS has been investing in the use of robotics in medical interventions, which improves the quality of the procedure and patient recovery.
  (a) In January 2024, the first robotic thyroidectomy was performed, at the Curry Cabral Hospital (an NHS hospital). This will revolutionise the way this common procedure is usually performed, allowing for a faster recovery and, because it is less invasive and aggressive, less significant physical sequelae.
  (b) In February 2024, the first paediatric surgery with the use of a robotic arm was performed (before that, the robotic had only been used in adult surgeries).
- During clinical trials, the recruitment of individuals or patients who fulfil the predetermined criteria outlined in the medicine study is essential. AI-based technologies play a crucial role in expediting, standardising and simplifying this selection process efficiently. Thus, researchers are now implementing AI algorithms on anonymised datasets to pinpoint clinical research centres housing patients suitable for the drugs under study.

Cloud data transformation

Many life sciences companies are now adopting cloud-based technologies to store their critical data remotely. This approach allows employees to access data from any location, at any time, while maintaining high levels of security. By utilising cloud infrastructure, these organisations are achieving greater operational flexibility, enabling faster decision-making and increasing overall efficiency.

Scientists at the Champalimaud Foundation have been working on the development of a cloud-based infrastructure to store health data for research purposes. This is the first time

such a system has been created in Portugal. The goal of the project is to establish a standardised method of storing patient information in the cloud, with appropriate anonymisation, to allow secure access for researchers worldwide. Eventually, this system could also be used by clinicians and patients, who will be able to access the information online from anywhere in the world.

Clinical trials – complying with demand and recent EU regulation

In recent years, Portugal has experienced a significant increase in the number and scale of clinical trials conducted in various therapeutic areas. As a result, Portugal has been identified as one of the "core countries" for clinical trials.

This growth in clinical research has attracted major pharmaceutical companies to invest in Portugal, leading to the country's economic development. However, the size of the industry and the increase in research activities requires adjustments in regulatory policies.

In an effort to promote the expansion of clinical research, the government issued Order No 1739/2024 on 14 February 2024. The order outlines a series of measures aimed at enabling Clinical Research Centres within the NHS to operate with increased capacity and autonomy by adopting new organisational forms.

Clinical trials for medicinal products are regulated by the Clinical Investigation Law (Law 21/2014 of 16 April). As of 31 January 2022, these trials must comply with the newest EU Regulation on Clinical Trials, which introduced the Clinical Trials Information System (CTIS). This system will be used for submitting, examining and overseeing all clinical trials in the European Union.

Starting from 31 January 2023, new submissions for clinical trials in the EU and the European Economic Area must be submitted under the CTIS. By 31 January 2025, all ongoing trials must be transferred to the CTIS. INFARMED (the National Authority of Medicines and Health Products) has recently urged all ongoing clinical trial sponsors to transition to the CTIS as soon as possible, to ease the process and avoid any suspensions or trial interruptions.

Patient protection – information on the prices of medicines

A new law, Decree-Law 128/2023, was issued in December 2023, amending the Legal Regime of Medicines for Human Use (Decree-Law No 176/2006, of 30 August), bringing significant changes to the information about medicine prices. The primary objective of this decree-law is to enhance the information provided to users when dispensing medicines by eliminating the reference to the retail price (PVP) on the packaging, which has been found to be of little importance and challenging to comprehend.

According to the law's recitals, the PVP appearance on the packaging does not usually reflect the actual cost of the medicine to the citizens, as there are too many variables that influence the final price, such as reimbursement and its varied application criteria. For that reason, eliminating the PVP on the packaging is intended to avoid providing misleading information and to avoid outdated information resulting from price changes. Instead, the government encourages other methods of accessing the pricing information, such as it being given by the pharmacies to the patient at the time of dispensing the medicine and being available by consulting the medicine search functionality of the INFARMED database.

For that reason, medicine packs distributed to pharmacies after 2 January 2024 no longer need to mention the PVP.

Environmental, social and governance (ESG) in the life sciences sector

Life sciences companies, including those based in Portugal, are facing increased scrutiny regarding their ESG policies.

With regard to the upcoming legislative elections in Portugal (March 2024) and the pressing need for sustainable practices in the health industry, the Portuguese Council for Health and Environment expressed its concerns and proposals the political parties should include in their agendas, issuing a public Manifest in January 2024. Such proposals include the promotion of a national strategy for the implementation of good sustainability practices, particularly in terms of energy efficiency, the use of water and transport, and the waste of packaging and materials.

To that end, efforts have been made to promote sustainable practices in the life sciences industry. The Champalimaud Foundation signed a partnership with Philips to halve its CO2 emissions, and partnered up with the Greenvolt Group to achieve carbon neutrality. Using the energy generated by solar panels at the Champalimaud Centre and shared by other Greenvolt Communities, the foundation aims to be the first healthcare institution in the world to consume only clean energy within five years.

Intellectual Property Litigation and Life Sciences

Unified Patent Court (UPC)

In 2023, Europe entered a new chapter in patent litigation with the launch of the new unitary patent (UP) and the establishment of the UPC on 1 June. This milestone represents a pivotal moment aimed at simplifying patent disputes and fostering commercial certainty for businesses across various sectors. The life sciences sector has become a significant focal point of litigation and attention in these early months following the entry into force of the UPC.

One notable trend in the early stages of the UPC's operation is the heightened involvement of big life sciences companies in patent disputes brought before the court, namely between big pharma corporations Amgen and Sanofi. Despite some initial predictions that those players would stay out of the big field in the first stages, the prominence of the life sciences sector in the UPC litigation underscores the importance of intellectual property protection in pharmaceuticals, biotechnology and medical devices.

Another interesting trend involves the use of protective letters, a legal figure not found in Portuguese law but allowed in the UPC under Rule 207 of the UPC's Rules of Procedure. A protective letter is typically submitted when an individual or entity anticipates the possibility of facing an application for provisional measures as a defendant in the UPC. Essentially, it serves as a proactive defence statement filed in advance to mitigate potential legal risks. This proactive action allows parties to address concerns regarding imminent legal proceedings and assert their position before the court. The increasing use of protective letters indicates a proactive strategy by companies preparing for a potential rise in preliminary injunctions within the UPC.

This trend highlights the importance of protecting intellectual property rights and proactively addressing potential disputes in patent law's constantly changing landscape, particularly in the UPC arena, with all its implications.

Furthermore, during the seven-year transitional period following the entry into force of the UPC Agreement, parties have flexibility in choosing the jurisdiction for actions involving classical European patents (excluding those with unitary effect). Article 83(1) of the UPC Agreement allows parties to bring such actions before national courts or other competent national authorities. Consequently, some companies are opting to pursue actions in national courts to avoid the potentially high litigation fees associated with the UPC.

This strategic decision, which has been embraced by several pharmaceutical companies in Portugal, underscores a practical approach aimed at navigating the transitional period effectively, weighting cost factors and litigation strategies within the evolving landscape of patent enforcement.

Although no lawsuits have yet been filed in the Lisbon Local Division, the judicial officer is actively handling cases in all divisions of the UPC. This highlights the efficiency and cohesion of the UPC's organisational structure, which operates like a well-oiled machine. The UPC's judicial officers' involvement in different divisions allows for streamlined patent litigation services across Europe, highlighting the importance of the organisational structure.

The Supplementary Protection Certificate (SPC) waiver

The process of developing medications and plant protection products involves significant research and investment, which highlights the need for additional protection for the underlying patent. The SPC is a specific right established to fulfil this purpose. It prolongs the exclusivity period of the pharmaceutical or plant protection product covered by a patent to make up for the time required to obtain initial administrative marketing authorisation.

The SPC Waiver Regulation of 2019 (Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019) has been introduced as an attempt to balance the threat of unfair monopolies and access to the market with the compliance of intellectual property rights. The regulation has allowed other companies (as generics) to export and store protected products before the certificate's expiry, provided that they notify the Industrial Property Authority and the SPC holder.

The SPC waiver legislation allows manufacturers of generics and biosimilars who produce their products outside the EEA and launch them right after the expiry of SPC protection to establish supply chains within the EEA during the SPC period of validity in order to prepare for the immediate launch after expiry.

However, recent trends of compliance with the SPC waiver Regulation might be surpassing the initial purpose for which it was designed. A recent Review of the SPC Manufacturing Waiver was published by Medicines for Europe (which represents the European generic, biosimilar and valued added pharmaceutical industries) concerning the recent integration of the waiver system.

Many companies are now using SPC waivers, and more than half of them have submitted at least one notification since the legislation was introduced. However, some companies are hesitant to manufacture due to concerns about potential "frivolous and abusive" litigation from SPC holders.

The report highlights various tactics used by SPC holders, including:

- initiating litigation based on hypothetical patents in export markets like the US; and
- misusing confidential data obtained through the SPC waiver system.

These actions can deter legitimate manufacturing activity under the SPC waiver system because of the potential cost of litigation.

For those reasons, the Report calls for urgent action to address abusive tactics against companies that are using the SPC waiver system. Measures proposed in the report aim to inhibit SPC holders from discouraging legitimate manufacturing activity under the SPC waiver system. This could involve interventions by courts, the European Commission and national competition authorities to uphold fair competition and protect manufacturers against abusive litigation.

Conclusion

Portugal's life sciences industry has been rapidly evolving in recent years, driven by a combination of factors such as innovation, societal demands and regulatory changes. The country is increasingly establishing itself as a hub for biotechnological advancement and clinical research, with a growing number of companies and institutions conducting cutting-edge research in fields such as genetics and biomedicine.

However, despite the sector's growth, there are still several challenges that need to be addressed, such as regulatory compliance, as the industry must adhere to strict regulations and guidelines to ensure safety and efficacy.

Sustainability is becoming an increasingly pressing issue, as the industry seeks to balance economic growth with environmental and social responsibility. This requires not only the adoption of eco-friendly technologies and practices but also a commitment to transparency, inclusivity and social impact.

To overcome these challenges and sustain its growth, Portugal's life sciences sector has been incorporating technological innovations such as AI and cloud-based data storage, which have the potential to transform the industry by enabling faster, more accurate data analysis, and improving patient outcomes. However, it is crucial that these technologies are implemented in a way that prioritises ethical considerations, regulatory compliance and sustainability imperatives.

Ultimately, Portugal's life sciences sector has the potential to make significant contributions to global healthcare and scientific progress.

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