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Life Sciences 2023

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Portugal: Trends and Developments

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Trends and Developments

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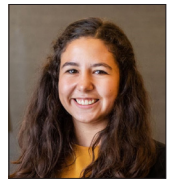

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Highlights

The life sciences sector has been improving at a fast pace, and the experience of the COVID-19 pandemic has had a very positive impact on the sector.

Companies continue to transform themselves and implement new measures based on digital models. Digital transformation is accelerating every part of the life sciences value chain and the way the sector deals with patients and clinical trials. Technology is also being used to store the data of companies and patients (highly sensitive data), and to accelerate companies' level of performance. Therefore, digital privacy and security must be a concern in the sector, and the digital transformation used to address this concern is seen as a challenge.

In Portugal, several important research initiatives in the sector should be highlighted due to their impact on worldwide trends – namely, those carried out by Fundação Champalimaund. Two new research centres have also been created.

In addition, ESG is expected to be a trend in the future as companies face increased trials and new global standards that should be taken into consideration.

The Unified Patent Court (UPC) will be a reality after ten years of discussions, and life sciences companies should review their portfolio of patents and IP strategy for the future, due to the several advantages of this court. The supplementary protection certificate (SPC) waiver is in place, and is being used by several blockbusters in the medicines market in Portugal.

Technology and Life Sciences

Clinical trials

The COVID-19 pandemic created the need to develop medicines and vaccines at a much faster pace than used to be the norm. Therefore, new processes and techniques were developed, which are now being applied to other drugs.

Also, with the pandemic restrictions, workarounds had to be found. Thus, remote monitoring and remote visits were top strategies for keeping clinical trials ongoing during the pandemic. This means that geography and business hours are no longer barriers to performing clinical trials, thanks to the new digital and virtual tools. Researchers have been finding ways to bring more people into trials through adaptive, decentralised and hybrid models, which leads to better results with more and more diversified subjects. This being said, many hospitals

and research institutions have started to include home-based reporting and to use tools such as telemedicine, sensor-based technologies and wearable medical devices.

In addition, adaptive trials using artificial intelligence were used to discover and compare potential treatments, which may start to be used during research and development of all kinds of medicines.

All this digitalisation of trials decreases the burden on patients as they no longer have to travel to participate; it also decreases the report subjectivity, due to the data being based on sensors and wearables instead of the sole reporting. This leads not only to there being more data, but also to it being more accurate.

Patient-centricity

The pandemic led to an increase in the importance of disease treatment for patients. Digital technologies enabled telemedicine to become broadly available, thus making treatment much faster and more cost-effective, and putting patients in charge of their own treatments.

Companies are also enhancing engagement with patients while developing new medicines, and are starting to understand that it is useful to involve patients in all phases of development, from brainstorming to launch. As time goes by, patients have been seen more than ever as an equal partner. Pharma companies are starting to reflect more of the patient's needs, building trust between companies and patients, and also providing better products that fulfil their targets' needs much better than before.

In addition, drug development is taking patients' experiences, needs and outcomes further into account, instead of the traditional parameters thought about when running clinical trials. For instance, factors like quality of life and physical and mental health are starting to be used as parameters for patients to provide feedback during clinical trials. This enhanced engagement allows companies to have access to more accurate and complete data, as it has led to the incorporation of patient experiences, resulting in better products and a life improvement for the community in general. This also leads to greater adherence to treatments, as the outcomes will consider more factors than the simple treatment of a specific symptom.

Cloud-first transformation

Many life sciences companies have been making efforts towards adopting technologies in which the main data is stored beyond their own premises, in a cloud. This transformation allows a company's workers to have access to information at any time and from anywhere, which has enabled businesses to run at a much faster and more effective pace.

It also empowers collaboration, because it allows every worker to have access to the most updated data for each document in real time. When dealing with sensitive matters like those treated in the life sciences area, and in a business field that has so many changes and constant progress, regularly updated data has been turning clouds into an important resource.

In addition, the value of working on a cloud-first basis can be maximised, with the usage of integrated information management systems, for example. This leads to more efficient usage of the available data, with faster and better outcomes.

Cybersecurity

With all the data involved in life sciences, from research and development to marketing, stock management and everything in between, and the digitalisation of this information, cybersecurity has become more and more of a concern. The risks of industrial espionage and regulatory fines are increasingly high, with data breaches becoming more common and courts being increasing open to using digital data as evidence.

Therefore, digital privacy and security have become a major concern, and have been developed through giving more information to workers, adopting zero-tolerance cybersecurity measures while developing and updating the data-managing software, and selecting what is the most critical data and who has access to that data, considering the potential impact if it is compromised.

Recent Relevant Research

The human brain

The understanding of the human brain and how it works has been a great focus of research, as it is so important to understand the whole human body, as well as human behaviour. For that reason, Fundação Champalimaund (an institution that performs research in cutting-edge areas and whose priority is to stimulate discoveries that benefit people, developing its activity in the areas of neuroscience and cancer) has been investing in research regarding this matter.

For instance, in January 2023, this foundation announced funding for a study to understand how the fruit fly brain computes and corrects trajectory errors, which has an impact on understanding the human brain with regards to physical orientation.

In February 2023, the Fundação Champalimaund and the University of Minho published a study which suggests that the brain works like a resonance chamber: ultra-fast, ultra-high-field magnetic resonance imaging performed in rats revealed that there are resonance waves in the brain that establish connections between distant brain areas, which are essential for the normal functioning of the brain. This research may create a new path to dealing with brain diseases, as it provides a better understanding of how the brain works both when healthy and when sick.

New research centres in Portugal

There has been great progress in biomedical investigation. However, although it is possible to cure cancer or diabetes in animals like rats, those diseases still cause great suffering and a lot of mortality in humans. It is believed that one of the reasons for that limited success is the lack of understanding of human biology and physiopathology on a cellular and molecular level.

Focusing on filling that gap, a new investigation centre is being developed by Nova University of Lisbon, in partnership with the Max Delbrück Centre in Berlin, run by researcher António Jacinto: the NOVA Institute for Medical Systems Biology (NIMSB). It will focus on the development of experimental models that are more similar to human tissues and organs, and with a better analysis to understand the outcome of those experiments. Fourteen new research groups will be created, in which researchers will access innovative technologies that provide unprecedented information on the generation, progression and treatment of diseases.

Following up on the digital trend, this new project foresees the usage of new technologies such as Artificial Intelligence being applied to the biomedicine and emerging multitopic meth-

odologies (ie, methods that combine genomic data with data from other modalities such as transcriptomics, epigenetics and proteomics, to measure gene expression, gene activation and protein levels). With these technologies, it is expected that the causes of diseases will be treated rather than symptoms, and that the early detection of diseases will be made possible, enhancing the chances for the patient to be cured.

Focusing more on the application of the research to hospitals and patients, another new research centre is being created inside the Portuguese Institute of Molecular Medicine – the IMM-Care – by Maria Manuel Mota, a researcher who has been researching malaria, with the main goal of stimulating clinical research for the benefit of society.

Environmental, Social and Governance (ESG)

Life sciences organisations, including those operating in Portugal, have been put under a lot of scrutiny regarding ESG policies, primarily related to employment hiring practices and manufacturing standards. Life sciences companies are accordingly expected to invest even more in ESG policies.

There is an increasing need for companies to be transparent with all stakeholders and to incorporate their perspectives into their decisions, which has the benefit of improving understanding of the consequences of a decision and minimising the risk of said decision by having support. This also increases the company's reputation. Building trust amongst the community is crucial to demonstrate the value of these companies, and that means being transparent regarding the ESG policies adopted.

Pharma companies have been focusing on making medicines more sustainable and reducing greenhouse gas emissions, particularly the emissions of supply chain companies. This is also becoming a legal obligation.

In November 2022, the European Union adopted the Corporate Sustainability Reporting Directive, which aims to strengthen the requirements of companies' reporting sustainability measures by broadening the categories of companies covered by the reporting requirements, to include qualitative and quantitative elements concerning sustainability impacts, and the extent to which sustainability issues affect development, growth and market positioning.

This directive has yet to be transposed in Portugal, but companies must start making efforts to comply with the legal rules in order to be prepared for the transposition.

Public institutions also consider this a concern. In January 2023, the Portuguese Council for Health and Environment expressed its position in favour of the creation of a global strategy to reduce the ecological footprint in the health sector, with goals such as hitting zero greenhouse gas emissions by 2035, which is important because this sector is responsible for 4.4% of such emissions.

Companies have become more concerned about social inequalities in clinical trials, as ensuring diversity expands access to better therapies, thereby building trust and promoting innovation. To this aim, strategies are being created, such as:

- the creation of research sites in non-traditional locations like community health centres

and pharmacies, to increase closeness to the communities and mutual trust;
- the establishment of relationships with the community, which might help to gather significant inputs; and
- the development of rationally and ethnically diverse pools of staff to ensure cultural competence and mindfulness of existing biases, which ensures that relevant inequalities are properly treated, thereby assuring the quality of the medicines and their adequacy to everyone.

Industrial Property in Life Sciences

The Unified Patent Court

The UPC is a major change in the European landscape and is the result of more than 20 years of attempts to create a united European patent system. If everything goes as planned, the UPC and Unitary Patent will enter into force in 2023.

Lisbon will host a local division, as well as the Patent Mediation and Arbitration Centre of the UPC. The decision-making process of this court is typically panel-based, and the expected uniformity of approach should be location-independent. Also, it is expected to integrate legal and technical expertise in its decisions. This court will be competent for all matters regarding the infringement and validity of unitary and classical European patents granted by the European Patent Office (EPO).

A European Patent with Unitary Effect will be a European patent granted in accordance with the requirements of the European Patent Convention, which, with a single application, produces effects in the territory of all member states that have signed the Agreement on a Unified Patent Court.

A challenge will arise concerning which strategies pharmaceutical companies (among others) will pursue regarding patents for reference medicines, as there are many advantages but also great risks to adhering to the European Patent with Unitary Effect and to the UPC.

SPC waiver

The time-consuming and costly research into medicines and plant protection products must be offset by additional protection for the basic patent. The SPC is the sui generis right created for this purpose. It increases the period of exclusivity of the pharmaceutical product or plant protection product covered by a patent, to compensate for the time that it has taken to get a first administrative marketing authorisation.

In 2019, the SPC Waiver Regulation entered into force, enabling other companies to export the protected product to third countries and, within the six months before the expiry of the certificate, to store or make for the purpose of storing the protected product, provided that the maker notifies the Industrial Property Authority of the relevant country and the SPC holder.

The transitional provisions for the application of the SPC waiver ended in July 2022. Since then, several notifications for either storing and/or exporting have been published in Portugal in relation to SPCs covering several blockbuster substances.

This means that this new option for generic medicine manufacturers to produce and store products before the expiry of the SPC is being used by companies, and it is a trend for the future.

It is worth noting that the articulation between the SPC and the Patent with Unitary Effect has not yet been made by the European Union.

However, changes are expected in this regard to avoid the holder of a European Patent with Unitary Effect needing to request a different SPC for every country individually.

The Use of Cannabis for Medical Purposes – Still an Opportunity in Portugal

The Portuguese legislation in force still reflects the legislature's strong concern about providing activities linked to cannabis. The discussion around the decriminalisation or legalisation of cannabis for recreational use is not over, but some developments made over the past year should be highlighted.

Such development contribute to the clarification of the regulatory steps for the cultivation of cannabis for medical purposes in Portugal.

Indeed, all drugs in Portugal require a licence from the National Authority of Medicines and Health Products, I.P. (INFARMED) before they can be launched on the market. INFARMED is an entity within the Portuguese Health Ministry that is responsible for the management, control and assessment of medicines and health products to secure general health.

Ministerial Order No 14/2022, of 5 January, amends some articles of Ministerial Order No 83/2021, of 15 April, which sets out the requirements for the instruction of applications and procedures regarding the granting of authorisations for the exercise of activities related to the cultivation, manufacture, wholesale trade, transport, circulation, import and export of medicines, preparations and substances based on the cannabis plant.

The recently introduced amendment is intended to address the insufficient regulation on some issues related to the cultivation of the cannabis plant for medical and non-medical purposes. Specifically, the amendment addresses the cultivation of hemp for industrial purposes, differentiating it from the cultivation of the cannabis plant for other purposes.

Therefore, for the wholesale trade of the plant or part of the plant, or active substances based on the cannabis plant for medicinal purposes, the list of requirements has been expanded to include the following:

- the full address and geographic location by co-ordinates of the facilities;
- a licence for the use of the storage facilities;
- a plan and description of the warehouse premises and the security measures implemented;
- a technical pharmaceutical manager;
- written procedures concerning the activities performed regarding the receipt of goods, storage, expedition, transport, records of traceability of the product from its acquisition to its expedition, and the qualification of suppliers and clients;
- certification of the security manager, to be issued by the Private Security Department of the Public Security Police Force, upon proof of the security manager's training and other requirements established in the legal regime of private security, and the criminal record must be issued for the purpose of the "lawful drug/psychotropic substances market";
- the term of responsibility issued by the person in charge of security; and
- the employment contract signed between the applicant and the security officer.

Conclusion

COVID-19 has had a permanent impact on all fields of activity, especially the life sciences sector, as it was a health issue that led to major

scientifical developments and created a different way to view the life sciences field and the way companies work in the sector. It has also accelerated the importance of new digital technologies in this field of activity, allowing faster and more cost-effective ways of working and achieving scientifical progress, which has led to important breakthroughs.

As the way of viewing and dealing with life sciences is also changing, there have been many legal changes that impact this field of activity, considering issues like ESG concerns and the methods of dealing with companies' industrial property.

Life sciences is therefore an area with increasing importance in Portugal, which is attracting more investment and being subjected to many policy measures to meet the currently fast-paced world and the importance of this area to people's lives.

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