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Life Sciences 2022

Portugal: Trends & Developments

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Trends and Developments

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COVID-19: the Other Side of the Coin

In the past two years, COVID-19 has been a recurring theme and it imposes itself on every analysis due to the transversality of its impact. The life sciences sector is not an exception, being one of the sectors that suffered an extraordinary and positive impact with the pandemic crise.

Today, and more than ever, strengthening the Portuguese National Health Service is essential, but the strategic focus on the health sector goes far beyond health care, recognising this sector as an important hub for the country's development.

Portugal has implemented the "Health Cluster Portugal" platform, which includes R&D pharmaceutical companies, hospitals, universities and government bodies. This platform is Oporto and aims to turn Portugal into a competitive player in the research, invention, developing, manufacturing and commercialisation of products and services of high added value. It currently holds approximately 170 members, embracing the entire field of life sciences in the country. Further, healthtech start-ups have been placed in the Portuguese market in both sections: digital health (ie, EyeConnect and Phast) and medical devices (ie, Pineal Technologies 3D and Cepha).

The quantified self is also a trend that calls the attention on data privacy issues. Challenges in the field of information security and data protection have emerged.

The pandemic has accelerated virtualisation in both consumer and clinical trial contexts giving rise to the growth of decentralised clinical trials. These changes give rise to a host of complex legal and regulatory aspects impacting both life sciences companies and their financial backers.

In Portugal, the National Authority of Medicines and Health IP's (INFARMED) Strategic Plan 2020–22 gives emphasis to the following key ideas and common concerns:

- availability and access to human and veterinary medicines;
- adoption of emerging technology (artificial intelligence and data analytics);
- support for innovation; and
- challenges associated with supply chains.

Infarmed's Relevant Data

According to INFARMED's data, in Portugal, the market for medicines and health products (medicines for human use, medical devices and cosmetics) is estimated to exceed EUR7.3 billion, representing approximately 3.5% of the national gross domestic product (GDP).

The number of clinical trials authorised in Portugal registered a slight drop of 7% compared to 2020, according to the most recent information. However, most of the registered data does not show major oscillations.

Phase III clinical trials continue to have the highest expression in Portugal, representing 57% of the total number of clinical trials submitted in 2021. However, in comparison with data from 2010, there is a significant increase in the number of investigator-initiated trials (phase I), which grew from 2% in 2010 to 22% in 2021.

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With regard to the authorship of the proposed and authorised trials, the pharmaceutical industry remains the major promoter of clinical research in Portugal. In 2021, 95% of trials submitted were initiated by the industry.

Regarding the therapeutic areas, there is no significant change between 2010–21, with clinical trials with antineoplastic, immunomodulatory, gastrointestinal, metabolic, as well as central nervous system and cardiovascular system drugs remaining predominant.

Life Sciences and Technology

The culture in health care is characterised by a wide-scale adoption of new digital and cognitive health technologies.

Development of robotics process automation in areas like drug discovery or data analysis is the new rule. Artificial intelligence has revolutionised health care through mining medical records, designing treatment plans, speeding up medical imaging and drug creation.

The legal and regulatory setting in Portugal is not yet prepared for the new technologies. However, some attempts have been made to accompany this evolution.

The Council of Ministers Resolution No 131/2021 approved the Digital Transformation Strategy for Public Administration 2021–26 and the respective Transversal Action Plan for the legislature.

This strategy aims to make public administration more responsive to the expectations of citizens and businesses, providing simpler, more integrated, and inclusive services, operating more efficiently, intelligently, and transparently, by exploiting the potential transformation of digital technologies and the intelligent use of data.

This project is based on six strategic lines of action:

- digital public services;
- data valorisation;
- reference architectures;
- information and communication technology (ICT) skills;
- ICT infrastructures and services; and
- security and trust.

Also significant is the activity of Portugal within the European network of health technologies (EUnetHTA) – a consortium represented by 13 European agencies, where INFARMED is included, which aims to improve the availability of innovative health technologies for citizens and strengthen the quality of health technology assessment at a European level, also embodying INFARMED's mission.

EUnetHTA 21 will continue the work conducted under the EUnetHTA joint cooperation (which ended in May 2021). The concluded agreement is intended to serve the new legal framework for co-operation in health technology assessment. In addition, joint clinical assessments will be carried out under the contract and joint scientific advice will be provided. This advice will run in parallel with the European Medicines Agency (EMA) for health technologies still in the clinical development phase.

In the next few years, it is foreseeable that investment in scientific research in the area of health technologies will increase.

Data as the New Healthcare Currency and Clinical Data Intelligence

In 2022, healthcare data is a national infrastructure priority and critical business asset, attracting significant funding. This sector is producing more data in more formats across more channels than ever before. Both traditional institu-

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tional health professionals and quantified self (QS) individuals are starting to find themselves in a whole new era of massively expanded data.

A newcomer challenge has been to mine the patient's medical record and make it readily accessible. Companies are interested in managing and accelerating regulatory filing for new medical entities to bring therapies quickly and efficiently to market.

Taking better control of clinical trial's data must be a priority for life sciences companies, who need information to enable researchers to develop more precision medicine and clinicians to predict patients' response to treatments, improving outcomes and health care productivity.

To that end, pharmaceutical companies are starting to use software mechanisms to efficiently capture data from all available sources and use it to develop better treatments and launch them faster. Effectively managing this data improves and accelerates the drug development process in areas such as drug discovery, clinical trial design, patient engagement and post-market surveillance.

Many solutions have emerged offering clinical trial management software with automated, intelligent capture and AI to help organisations enhance meta-analysis in clinical trial documents. The use of clinical data intelligence allows companies to take advantage of AI technology to improve data quality, reduce time to submission and get to market faster.

Due to the plummeting cost of sequencing and Internet-based data storage, many of these data streams are now available directly to consumers.

One of the goals presented by INFARMED to the year of 2022 is precisely the use of big data, data science and artificial intelligence so we expect that Portugal will be able to develop more "intelligent" information systems.

Clinical Trials

Decentralised trials

While laboratory and plant work may require a controlled environment, there's a range of other work that can be done remotely. Hybrid ways of working present obvious benefits for life sciences enterprise functions.

One of these examples is the adoption of decentralised clinical trials, catalysed and encouraged by the COVID-19 pandemic. Since the health-system resources became consumed by COVID-19-related care and travel became limited by physical distancing, patients' access to trial sites decreased.

This method of conducting trials remotely and in participants' homes is preferred by sponsors, who are continually seeking to make clinical trials faster and to improve the experience for patients and physicians. Decentralised trials offer a patient-centric approach, benefiting sponsors by accelerating clinical development, enabling more representative patient access, and developing a stronger evidence package than traditional trials.

Thus, instead of using the traditional paradigm of bringing patients to a trial site, trial decentralisation is focused on bringing trial's activities to the patients.

This will be the future paradigm as it broadens trial access to reach a larger number and potentially a more diverse pool of patients.

Launch of the Portugal Clinical Trials Portal

Portugal aims to be more competitive in clinical research.

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On the 24th of November of 2021 took place the launch session of the Portugal Clinical Trials Portal, an initiative of APIFARMA, the Portuguese Pharmaceutical Industry Association, in partnership with the Agency for Clinical Research and Biomedical Innovation (AICIB).

This new digital platform aims to contribute to the development of clinical research conducted in Portugal and, consequently, to the growth of data presented by INFARMED (epidemiological data of the country, news, clinical studies, contacts and clinical research updates).

This tool makes it possible to:

- consult a set of global indicators that allow to obtain an overview of clinical trials in Portugal;
- access in real time to the database of clinical trials underway in Portugal with details by pathology, region, phase and status of the study;
- understand the main players and the most critical phases of the submission and approval process of a clinical trial in Portugal; and
- consult accurate and up-to-date epidemiological data.

This platform asserts itself as a tool to support science and the development of more and better research centres in Portugal and wants to speed up the recruitment of people with disease, boost the speed in obtaining results and access to innovative medicines, providing greater quality of life and longevity to the population.

Industrialisation

The life sciences sector is becoming more and more industrialised.

With the ever-accelerating pace of change in the life sciences industry, a new era of competition has arrived as pharmaceutical companies feel the need to compete on their technology resources to be faster and efficient.

To meet accelerated product development cycles, the life sciences industry is seeking advanced cognitive technologies to improve the productivity, speed, and compliance of core processes. Companies also need to rapidly adjust to new ways of working in terms of connectivity, collaboration and the tools and platforms that enable them.

Besides focusing on architecture based on integrated business, technology and digital strategy, life sciences leaders are scaling their individual digital twin projects into networks of intelligent twins – living models of entire factories, product life cycles and end-to-end supply chains. These models create continuous threads of data that will soon be essential to every enterprise's digital strategy, allowing companies to innovate, reduce costs and contain risks at deployment.

Quantified Self

A key contemporary trend emerging in big data science is the quantified self (QS), ie, individuals engaged in the self-tracking of any kind of biological, physical, behavioural, or environmental information.

Software companies have been betting on innovation through apps that are revolutionising the lives of consumers of the "genome generation" who want to know more about their genetic profile, the diseases they have or might develop, and the effectiveness of health interventions.

There is a set of technologies such as wearable devices that monitor a user and collect various analytics (such as heart rate and blood pressure, caloric intake, sleep quality, physical activity, time spent playing video games and other factors involved in personal well-being), or even information and data about themselves to get

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the best treatment at a time, place and cost convenient to them. Genetic testing and other services have also become popular.

Quantified-self tools are increasingly collecting more personal data of users, storing them within the cloud and starting to consolidate data from different services. These techniques often involve the gathering of what would be considered "health information" according to legal definitions and may have implications on data protection privacy.

Although health data streams can contribute to the creation of a valuable public good that is usable by all, especially because it can be used in medical-related fields to predict health patterns or aide in genomic studies, it also brings up problems related to data protection privacy issues.

A new challenge is, therefore, to explore the legal and regulatory framework for self-quantified health information and wearable devices and determines the extent to which this framework addresses privacy and other concerns that these techniques engender.

It will also be interesting to watch the development of privacy-preserving QS tools.

Medicines Advertising

Advertising of medicines is subject to the legal regime provided for in the Medicines Statute, Decree-Law No 176/2006, of 30 August 2006, and, subsidiarily, the provisions of the Advertising Code (Decree-Law No 330/90, of 23 October 1990) that establishes the rules applicable to advertising in general. Also worth mentioning is Decree-Law No 5/2017, of 6 January 2017, which establishes the general principles for the advertising of medicines and medical devices.

The latest change to the legal framework of medicines for human use, also known as the Medicines Statute, was published on 19 May 2021, and it has to do with the prohibition of advertising price reductions on medicines.

The Decree-Law No 26/2021, which came into force on 1 July 2021, determines the prohibition of all forms of advertising of discounts on the price of three types of medicines: prescription medicines, medicines subsidised by the Portuguese National Health Service or medicines containing narcotic or psychotropic substances.

Therefore, in addition to the legislation already into force concerning the prohibition of advertising of these types of medicines already provided for in the Medicines Statute, there is now a prohibition on advertising discounts on the price of medicines whose advertising was already banned.

Pharmacies are still obliged to visibly disclose relevant information in their relations with customers, which includes any discounts they grant on the price of medicines, but they shall not do so in the form of advertising to the general public.

The reasons for this legislation are related to the protection of public health, to the disadvantages in terms of competition between pharmacies and to the repercussions that discounts can have on equal access to medicines for the population.

It should be noted that, for the purposes of the scope of the prohibition established herein, advertising of medicinal products comprises any form of information, canvassing or inducement that has the object or effect of promoting the prescription, dispensing, sale, purchase or consumption, particularly by the general public, wholesale distributors and health professionals.

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Opportunities for Cannabis in Portugal

The influence of foreign trends and research into the potential benefits of the use of the substance for medicinal purposes have contributed to the limited decriminalisation of cannabis for medicinal purposes in Portugal.

Whereas the recreational use of cannabis is not permitted by law (it even constitutes a crime), industrial ad medicinal use is allowed if some very specific requirements are fulfilled, and only under certain circumstances.

For the medicinal use, the regulatory framework includes:

- Law No 33/2018 of 18 July 2018, that establishes the legal framework for the use of medicines, preparations and substances based on the cannabis plant for medicinal purposes;
- Decree-Law No 8/2019, of 15 January 2019, which regulates the activities of cultivation, production, extraction and manufacture, wholesale trade, import and export, transit, acquisition, sale and delivery of medicines, as well as the placing on the market of medicines and preparations and substances based on the cannabis plant intended for human use for medicinal purposes;
- Ordinance No 44 – A/2019, of 31 January 2019, that establishes the mechanisms under which the price of medicines and preparations and substances based on the cannabis plant intended for medical purposes should be set.

Regarding industrial use, the Regulation No 61/94, of 12 October 1994, lays down rules on the control of the licit market in narcotic drugs, psychotropic substances, precursors, and other chemical products that can be used in the manufacture of drugs.

It is expressly provided that medicines that use cannabis as a component, are required to have an MA issued by INFARMED, under the terms of the DL 176/06, while cannabis-based preparations or substances for the manufacture of medicines are required to obtain an authorization of placement in the market under the terms of the DL 8/2019, also under the responsibility of INFARMED.

Furthermore, in January 2019, a resolution of INFARMED's Board of Directors established the first seven therapeutic indications for preparations and substances based on medical cannabis, mostly related to pain pathologies, such as multiple sclerosis, oncology, and epilepsy.

In 2021, the Portuguese Parliament once again discussed the liberalisation of cannabis for personal use. Legislative proposals have been submitted by the Portuguese parliamentary parties *Bloco de Esquerda* ("Left Block") and *Iniciativa Liberal* ("Liberal Initiative") and intend to allow the consumption of recreational cannabis, without prescription, under certain circumstances.

Finally, on 5 January 2022 the Ministerial Order No 14/2022 was published to introduce the first amendment to Ministerial Order 83/2021 of 15 April 2021. The original Ministerial Order set out the requirements and procedures for granting authorisations for activities relating to the cultivation, manufacture, wholesale trade, transport, circulation, import and export of medicines, preparations and substances made from the cannabis plant.

The Portuguese legislation in force still reflects a strong concern of the legislator in providing this activity with security and strict control, not only by the competent regulatory authorities, but also by the criminal police bodies. The medicinal and industrial use of cannabis are part of a controlled

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system where INFARMED is the competent regulatory authority.

The penalty for trafficking (production/cultivation, distribution and sale of the substances known as "drugs") is placed at the level of those corresponding to the most violent crimes foreseen in the penal code, starting, in its simple form, that is, without aggravation, at four years of prison. Thus, according to Portuguese law, it is more serious to cultivate cannabis than to organise a kidnapping or hostage taking, or even practice a violent sexual coercion.

Nevertheless, the evolutionary steps that Portugal has taken cannot be ignored. It is important to remind that the discussion under decriminalisation or legalisation of cannabis for recreational use is not over.

The pharmaceutical industry has a vested interest that the legislation contributes to the promotion of research and clinical trials. They seek the development of medicines, their approval and subsequent introduction on the market.

At this stage, we may affirm that Portugal has started to build its own medicinal cannabis market.

New Regulations – Honourable Mentions

Given that regulations, unlike directives, are directly applicable and do not need to be transposed into national law, it is relevant to mention some of those new diplomas.

- With the entry into force of the new Regulation on Medical Devices (EU) 2017/745 (MDR) and the Regulation on In Vitro Diagnostic Medical Devices (IVD), new rules will be applied aiming at improved vigilance, market surveillance and traceability, as well as ensuring that these products reflect the latest scientific and technological state-of-the-art. This legislation also provides more transparency and legal certainty for manufacturers and aims to strengthen international competitiveness and innovation in the sector. On 26 May 2021, the Medical Devices Regulation became fully applicable after the transition period. The corresponding date of application of the In Vitro Diagnostic Medical Devices Regulation (IVDMR), Regulation (EU) 2017/746 remains in May 2022.

- Regulation (EU) 536/2014 of the Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use came into force on 31 January 2022. The Regulation was adopted by the European Parliament in 2014 and released in May of the same year. It was subsequently officially published in the Official Journal of the European Union on 31 July 2021 and came into force six months after that date.
- On 28 January 2022, the Regulation (EU) No 2019/4 of the Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed ("Medicated Feed Regulation") and the Regulation (EU) No 2019/6 of the Parliament and of the Council of 11 December 2018 on veterinary medicinal products ("Regulation on Veterinary Medicinal Products (VMPs)") entered into force.

The regulations now published will allow the legal framework to be adapted to the practical reality of this sector of activity.

Conclusion

The global life sciences industry is evolving at an extraordinary rate, and we can say, with some degree of certainty, that COVID-19 was its driving force.

Health is undoubtedly the core sector of post-pandemic economic recovery and investors have

not closed their eyes to this. Several changes and alterations in habits have been witnessed, motivated by the need to create quick reaction responses to future adversities. The times ahead will also be shaped by an exponential growth of industrialisation and technologies in this sector, allied to combined services from the fields of science, economics, and information technology.

The area of life sciences is therefore a strategic investment and priority area that stands out in the design of future policy measures in Portugal.

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