



Stepping into a new digital era for life sciences | what's next for the industry

To say *today is an era of opportunity but also risk for the Life Sciences (LS) companies* might be an understatement. During the COVID-19 era, LS companies took pride in having successfully addressed the emerging medical needs of the population under immense pressure. Building on their achievements in providing timely solutions to patients in need, the momentum is now for LS companies to build upon their accomplishments and apply the lessons learned to achieve future success.

Pharmaceutical, medical device, biotech and other companies of the LS sector are all identifying the continued technological advancement as a top opportunity to use technology to solve complex health challenges. Simultaneously, established tech companies like Amazon, Google and Microsoft are vigorously targeting healthcare as a further opportunity to grow their business. This trend is driven by the integration of AI, machine learning and other cutting-edge technologies which are being employed across a wide range of applications such as telemedicine, digital therapeutics, diagnostic imaging and disease prediction, aiming to boost patient care while cutting down on costs and resources. LS companies are increasingly turning to AI and other digital tools in an attempt to accelerate and improve traditional processes to-

wards a more efficient system, extending from the identification of new products to the design of clinical trials, management of supply chains and provision of remote services to the patients.

This merger of digital technology and healthcare is also marked by a patient-centric approach, as witnessed through the variety of tech-enabled applications currently in the market and in the pipeline. Healthcare is thus rendered more accessible and personalised, empowering individuals to oversee and monitor their health effortlessly.

1. The cultural shift

The current transition to digital healthcare is not only technological but

also cultural, changing the traditional framework of patient-doctor relationships. HCPs are surrendering their sole proprietorship over medical knowledge and start working hand in hand with patients, involving them actively in the decision making and handling of their condition. Patients move from being passive subjects, to proactive, informed and empowered individuals, while wearables, health apps and various online platforms provide real-time data and a vast amount of information, allowing patients to monitor their health continuously and LS companies to build upon patient centricity and optimisation of healthcare solutions.

2. Personalised healthcare

Personalised healthcare leverages advancements in technology and data analytics to offer more precise, predictable, and preventive outcomes tailored to the individual characteristics, needs, and preferences of a particular patient. Such an insight shall permit LS companies and HCPs to design and implement treatment options that are more targeted and aligned with each individual's unique characteristics, thereby significantly enhancing the efficacy and safety of medical care.

3. Remote healthcare

Patients, armed with digital health tools, are becoming all the more so, a point of interest for healthcare organisations and LS companies, reducing the dependency on traditional hospital set-ups. A step towards the right direction in implementing remote care outside the hospital setup is Greece's new Law 4931/2022 which allows for at-home hospitalisation for

certain categories of patients. Although this is an important first step, the transformation needs also to be significantly complemented by the integration of digital health technologies, notably wearable devices, telemedicine and solutions like at-home diagnostic kits, in the core of the legal framework, so as to allow more flexibility to HCPs and patients to proceed to medical acts and take care of their health or disease at home; something that was previously impossible without visiting a hospital or clinic. The new set up shall allow for more efficient disease handling and communication between patients and healthcare providers without the necessity for in person visits. While concerns about remote healthcare exist at a policy-making level, the overarching target is to leverage telemedicine to mitigate shortages in resources and lack of hospitalisation capacities in the traditional hospital framework. In this context the EU eHealth Action invites Member States to work on a common vision at both EU and national level: to strengthen the use of information and communication technologies in health development.

4. Sustainable goals

Additionally, remote healthcare through digital means also intersects with broader goals like decarbonising patient pathways. The shift to paperless e-prescriptions and remote monitoring and care, plays part in the larger narrative of fostering a more sustainable and environmentally friendly healthcare ecosystem. As remote healthcare becomes embedded in the healthcare system, a significant reduction in the carbon footprint associated with traditional healthcare practices is anticipated.

While tech-related innovations show impressive results, the long-established ways of LS companies retain many advantages. These include human and economic capital, scientific expertise, know-how and experience, regulatory expertise and established commercial teams. However, it is possible and arguably sought after, to combine the best of both worlds. Adapting the traditional *modus operandi* to incorporate the merits of digital healthcare is feasible but requires a long-term commitment to invest time and effort while adhering to existing and forthcoming rules and obligations.

What shall LS companies need to do?

To get started (or even to continue), an LS company could adopt a few key first steps in its way to implement a tech/digital targeted approach:

- a. adopt a clear digital and/or AI strategy covering all functions and implementation of cross functional roadmaps;
- b. safeguard that high-quality data is obtained and used appropriately and in conformity to legal and compliance mandates;
- c. implement data governance and data security policies;
- d. seek partnerships with partners who are tech/AI literate so as to safely integrate AI and digital tools in existing processes;
- e. invest in the acquisition and development of new digital skills and know-how;
- f. maintain and strengthen compliance and regulatory checks to cross check

and complement AI generated solutions so as to safeguard compliance with applicable laws.

The Greek reality and roadblocks

The remote provision of healthcare services through digital means in Greece is currently offered in principle almost exclusively by the public sector, through the NHS hospitals, albeit under a very concise legislative framework. The only provision that regulates the provision of telemedicine services in Greece is Article 66 § 16 of Law 3984/2011, which regulates various other matters that relate to the operation of public hospitals. In contrast, the provision of healthcare through digital means by the private sector, remains largely unregulated. In fact, the provision of healthcare remotely through telemedicine has not been welcomed in practice, given that an in-person consultation with the treating physician is seen to date as a prerequisite for the prompt delivery of a medical service.

It is thus largely accepted by the Greek jurisprudence that it is the sole responsibility of the treating physician to provide medical services to patient remotely, thereby giving rise to various risks and considerations to be taken into account. In this context, the provision of medical services through electronic/digital means could:

- a. be considered as a "street" practice and therefore incur sanctions when it concerns patients who live outside the territorial boundaries of the relevant area where the physician is licenced/registered,
- b. e-prescription and issuance of medical certificates or advice may be in

conflict with the relevant guidelines that have been issued by the EOPYY and dictate the prior physical consultation with the physician and

- c. in case of wrong diagnosis / treatment the physician could be held liable due to the failure to perform a prior personal clinical examination.

As regards AI, in Greece, Law 4961/2022 which has been only recently enacted has introduced new obligations for certain companies that use AI systems in the context of consumer profiling or so as to, for example, evaluate their partners. LS companies falling with the scope of said law need to educate themselves on the new rules and safeguard compliance thereof since in case of non-compliance both administrative and criminal sanctions may be incurred.

The integration of digital tools in the provision of healthcare solutions is not without its challenges. Navigating through the complexities of the relevant laws and regulations remains a significant hurdle, as there are significant roadblocks ahead. From constantly changing regulations, to the implementation of

new ones such as the new AI Act and the EU Product Liability Directive, the LS companies must prepare now for the new obligations to come and simultaneously ensure compliance with current rules and regulations in place, regarding inter alia, the use of AI, digital tools, telemedicine and other tech related fields.

Given the prevailing conditions and the undeniable state of need, until solid legislative frameworks are established, LS companies are urged to seek expert collaborations and legal guidance on the practical implementation of the digital solutions that the technology has to offer.

Contact us



Nefelie Charalabopoulou
Partner

n.charalabopoulou@zeya.com



Natalia Kapsi
Senior Associate

n.kapsi@zeya.com

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280 Kifissias Ave., 152 32 Halandri, Athens, Greece
newsletters@zeya.com
Tel.: (+30) 210 696.70.00 | Fax: (+30) 210 699.46.40

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